END STAGE RENAL DISEASE PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

NINETY-SEVENTH CONGRESS

FIRST SESSION

SEPTEMBER 28, 1981

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END STAGE RENAL DISEASE PROGRAM

MONDAY, SEPTEMBER 28, 1981

U.S. SENATE,
SUBCOMMITTEE ON HEALTH OF THE FINANCE COMMITTEE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 2 p.m., in room 2221, Dirksen Senate Office Building, Hon. David Durenberger (chairman of the subcommittee) presiding.

Present: Senators Durenberger and Baucus.

[The committee press release and statements of Senators Dole and Baucus follow:]

[Press Release, Committee on Finance, U.S. Senate]

FINANCE SUBCOMMITTEE ON HEALTH SETS HEARING ON THE END STAGE RENAL DISEASE PROGRAM

The Honorable Dave Durenberger (R., Minnesota), Chairman of the Subcommittee on Health of the Committee on Finance, announced today that the Subcommittee will hold a two-part hearing beginning on Monday, September 28 to review the End Stage Renal Disease (ESRD) program. The hearing will begin at 2 p.m. in Room 2221 of the Dirksen Senate Office Building. The second day of hearings is tentatively scheduled for October.

Senator Durenberger noted that "although the ESRD program has been extremely successful in providing access to the medical technology needed to treat individuals with permanent kidney failure, an examination of the way that objective is being achieved is warranted in light of the growing cost of the program coupled with limited resources. The hearing will provide the Subcommittee with an opportunity to examine how effectively the program is being operated and managed as well as review the reimbursement rates to providers of services. Program operations and management, including the role of the network, will be the subject of part 1 of the hearing. Part 2, which is being scheduled for October, will consider the equity and effectiveness of the reismbursement rate structure."

Senator Durenberger went on to say that the Subcommittee would like to hear from both patient and provider groups as well as the administration. Specifically, the Subcommittee expects to hear testimony at the September 28 hearing which addresses:

The impact the certificate-of-need process has on patients, providers, and costs; the role of the networks (present and future); the identification and prevention of abuses; the availability and need for clinical and program data; the implementation and results of mandated studies and experiments; the effects of past and present program reorganizations; the impact of staffing levels and training on costs and quality of care; the capabilities of intermediaries and carriers to control costs; and patient access to the facilities, treatment modalities, and physicians.

Requests to testify.—Witnesses who desire to testify at the hearing must submit a written request to Robert E. Lighthizer, Chief Counsel, Committee on Finance, Room 2227 Dirksen Senate Office Building, Washington, D.C. 20510, to be received no later than noon on Monday, September 21, 1981. Witnesses will be notified as soon as practicable thereafter whether it has been possible to schedule them to present oral testimony. If for some reason a witness is unable to appear at the time scheduled, he may file a written statement for the record in lieu of the personal appearance. In such a case, a witness should notify the Committee of his inability to appear as soon as possible.

Consolidated testimony.—Senator Durenberger urges all witnesses who have a common position or who have the same general interest to consolidate their testimony and designate a single spokesman to present their common viewpoint orally to the Subcommittee. This procedure will enable the Subcommittee to receive a wider expression of views than it might otherwise obtain. Senator Durenberger urges that all witnesses exert a maximum effort to consolidate and coordinate their statements.

Legislative Reorganization Act.—Senator Durenberger stated that the Legislative Reorganization Act of 1946, as amended, requires all witnesses appearing before the Committees of Congress "to file in advance written statements of their proposed testimony, and to limit their oral presentations to brief summaries of their argument."

Witnesses scheduled to testify should comply with the following rules:

(1) All witnesses must submit written statements of their testimony.

(2) Written statements must be typed on letter-size paper (not legal size) and at least *100 copies* must be delivered not later than noon on Friday, September 25, 1981.

(3) All witnesses must include with their written statements a summary of the principal points included in the statement.

(4) Witnesses should not read their written statements to the Subcommittee, but ought instead to confine their oral presentations to a summary of the points included in the statement.

(5) Not more than 5 minutes will be allowed for the oral summary.

Written statements.—Witnesses who are not scheduled to make an oral presentation, and others who desire to present their views to the Subcommittee, are urged to prepare a written statement for submission and inclusion in the printed record of the hearing. These written statements should be typewritten, not more than 25 double-spaced pages in length, and mailed with five (5) copies to Robert E. Lighthizer, Chief Counsel, Committee on Finance, Room 2227, Dirksen Senate Office Building, Washington, D.C. 20510, not later than Friday, October 9, 1981. On the first page of your written statement please indicate the date and subject of the hearing.

STATEMENT OF SENATOR BOB DOLE

Like so many others, I am particularly concerned over the alarming increases in the cost of the ESRD program and am equally concerned that patients receive high-quality care.

The cost of this program has been frequently underestimated. In 1972, when the creation of the ESRD program was being debated in the Senate, we heard cost estimates of $75 million for the first full year of the program and an annual cost of $250 million by the end of the fourth year. In fact, actual program costs were more than three times greater than these estimates for these periods.

Congress has sought to contain costs by mandating that the Secretary conduct various cost-saving experiments and establishing incentives to encourage greater use of less expensive treatment modalities. Yet we see an escalation in program costs from $283 million in 1974 to $1.4 billion in 1980. Perhaps even more alarming are the projected program costs of $2.7 billion by 1985, as noted by the Chairman, and estimates of $3.4 billion by 1990 and $4.5 billion by 1995.

I do not want my concern for the cost of this program to overshadow my interest in quality care being provided to patients now and in the future. However, we certainly expect that the care provided justifies this significant expenditure of Federal resources.

I look forward to hearing from our witnesses today—particularly those who are patients of the program and representatives of patient organizations.

OPENING STATEMENT OF THE HONORABLE MAX BAUCUS

Few pieces of legislation have been enacted that have had a more direct or more decisive impact on the lives of its beneficiaries than the ESRD progam. People who could afford life giving dialysis treatment numbered only a few thousand when the law was passed in 1972. Today, almost 65,000 patients are being treated.

But at the same time it has become clear that the program is plagued by problems.

The Congress owes a special obligation to remedy these problems—not only because of the program's crucial importance to those it serves, and not only because of the increasing burden the ESRD program is placing on our already weakened social security system.

We owe a special obligation to the ESRD program because it is almost entirely of the Federal Government's own making. Since medicare pays for the great majority of the ESRD services that are provided in this Country, it is Government that determines which facilities will be economically viable, the standard of quality they must meet, and how much they are to be paid.

I am looking forward to hearing from the witnesses today of their appraisal of the program and its problems and their recommendations for improvements.

Senator **Durenberger**. The hearing will come to order. I apologize for being late. I was supposed to vote on the floor and I was hoping that it would come before 2 o'clock rather than after. I appreciate your patience.

This is the first of two oversight hearings on the end-stage renal disease program. Prior to 1972, Government efforts to aid individuals with chronic renal failure were very limited. During the sixties, the high cost of dialysis and the limited number of dialysis machines created significant barriers to the treatment of end-stage renal disease patients. As a result, local governments established committees to determine which patients would be allowed access to the few dialysis machines available.

Fortunately, such decisions are no longer necessary. Public Law 92-603, enacted in October 1972, extended medicare coverage for kidney dialysis treatment for kidney transplant patients with end-stage renal disease. As a result, cost and the availability of dialysis machines are no longer the barriers they once were. However, the number of individuals that enrolled in the program and the program costs have increased significantly. It is expected to grow in future years.

The average annual enrollment has grown from 19,000 in 1974 to nearly 56,000 in 1979. The 1979 population reflects a 16-percent increase over that of 1978. Projections indicate an average annual enrollment of nearly 85,000 by 1985.

Benefit payments of $283 million in 1974 have grown to about $1.1 billion in 1979 and are expected to reach $2.7 billion by 1985.

In light of the rapid growth of program costs and the number of individuals served, coupled with limited Federal resources, the Subcommittee on Health has decided that it would be most appropriate to conduct an oversight hearing. The hearing will be conducted in two parts, as I indicated. The first, being held today, will focus on program operation and management concerns relating to the effect of the certificate of need process on patients, providers and cost; the impact of department organization on the program; the role of and need for networks; the need for adequate and reliable program data; patient access to facilities; treatment modalities; the physicians; and the results of the several studies and experiments which were mandated in 1978.

The second part, scheduled for late October, will consider the equity and appropriateness of the reimbursement rate structure.

This subcommittee will be particularly interested in the department's new reimbursement rate. We would hope that today's hearing would help us to assess the effectiveness of this program's operation and management, and to assist us in identifying the need for any refinements to the current legislation.

Toward this end, we have invited administration representatives, patient groups, and several other interested individuals and organizations to testify today.

Our first witness will be the Administrator of the Health Care Financing Administration, the Department of Health and Human Services, Dr. Carolyne Davis. Carolyne, welcome.

STATEMENT OF DR. CAROLYNE K. DAVIS, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION (HCFA), DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY DR. JAMES F. DONOVAN, ASSOCIATE ADMINISTRATOR FOR MANAGEMENT AND SUPPORT SERVICES, HCFA; AND SPENCER SCHRON, DIRECTOR, OFFICE OF END STAGE RENAL DISEASE PROGRAM, HCFA

Dr. **Davis**. Thank you, Mr. Chairman.

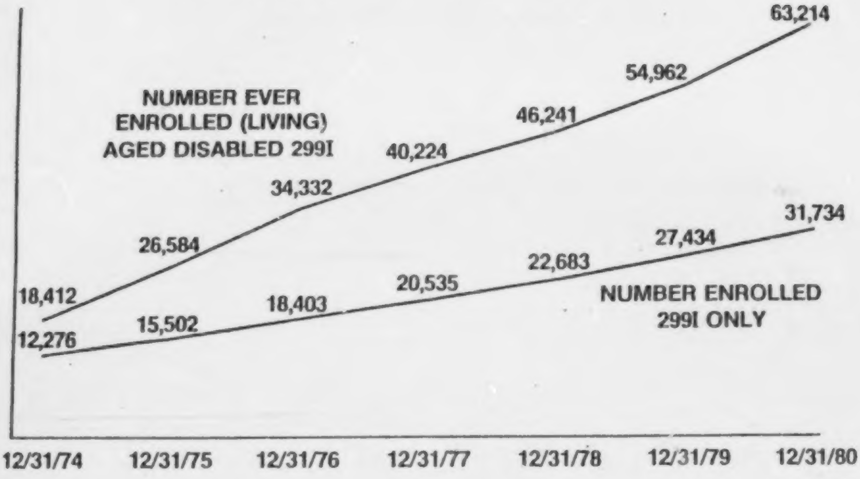
I am Carolyne Davis, the Administrator of the Health Care Financing Administration. And with me today, on my left, is Dr. Jim Donovan, the Associate Administrator for Management and Support Services of HCFA, and on my right is Mr. Spencer Schron, who is the Director of the Office of End Stage Renal Disease program, HCFA.

We are pleased to be with you to discuss the medicare end-stage renal disease [ESRD] program. As you requested, I will discuss the operation and management of the program today with the understanding that the reimbursement issues will be the subject of a subsequent hearing.

To place the operation in perspective, and as a followup to your opening statement, I would like to outline the growth of the program since its inception 8 years ago.

Our first chart here indicates the growth of the program in terms of the beneficiary population from 1974, which was the first full year of operation, until 1980. [Chart 1 attached.]

CHART 1



ALL ESRD* MEDICARE ENROLLED BENEFICIARIES

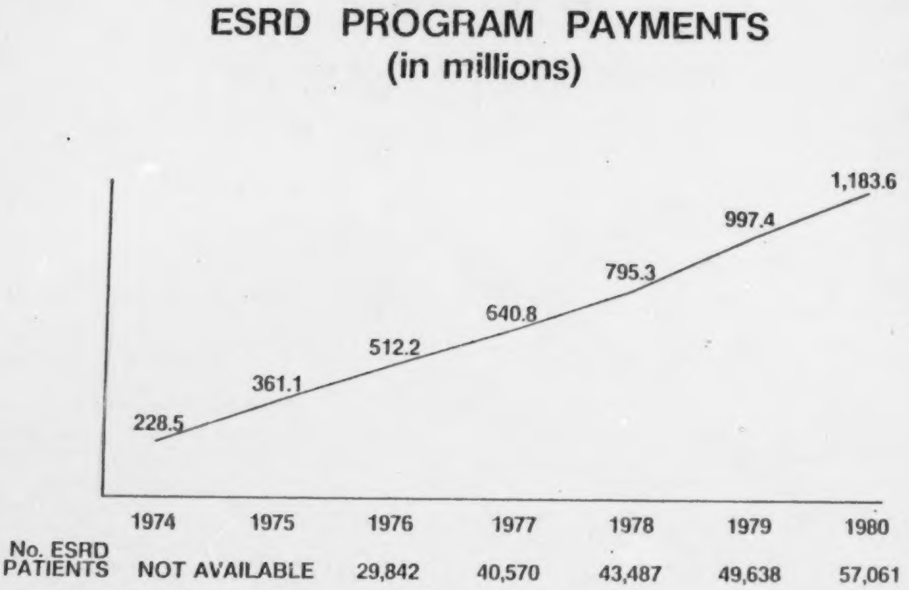
* 2991 REFERS TO BENEFICIARIES WHO ARE ENTITLED TO MEDICARE BENEFITS SOLEY ON THE BASIS OF HAVING END-STAGE RENAL DISEASE

As you can see, in 1974 there were approximately 18,412 ESRD beneficiaries. The number of beneficiaries then steadily increased year by year with an average annual increase of about 20 percent. So that by the end of 1980, there were 63,214 beneficiaries or, roughly, some 3½ times the original number.

I might add that the ESRD program requirements for medicare eligibility are really quite broad, and virtually the entire population of dialysis and transplant patients are covered under the program. Roughly 93 percent of all ESRD patients have medicare coverage.

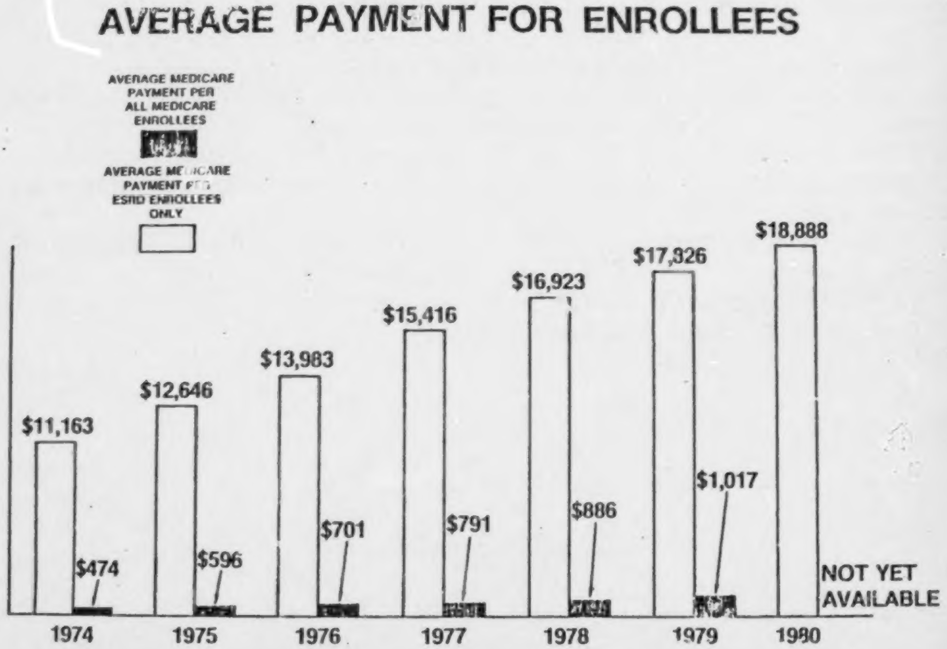
The second chart indicates the program expenditures in comparison to the growth in ESRD patients. [Chart 2 attached.] They grew from $228.5 million in 1974, which again is the first full year of operation, to about $1.2 billion in 1980.

CHART 2


ESRD PROGRAM PAYMENTS (in millions)

There has likewise been a dramatic increase in the average cost per ESRD patient. The third chart indicates that growth. [Chart 3 attached.]

CHART 3


AVERAGE PAYMENT FOR ENROLLEES

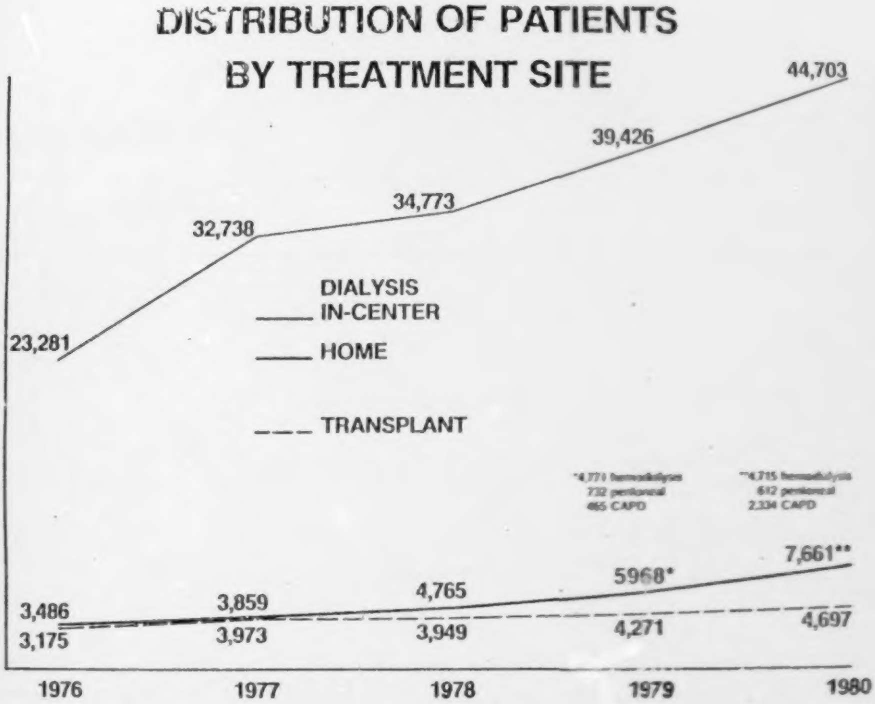
In 1974, the average cost per ESRD patient was $11,163. This per capita cost increased to $18,888 in 1980, or roughly an increase of 69 percent over the 1974 figure.

The ESRD beneficiaries, however, represent less than one-quarter of 1 percent of all medicare beneficiaries. And yet, as you can see, this one-quarter of 1 percent accounts for approximately 10 percent of all medicare part B reimbursement.

Our actuaries have estimated that by 1984 the number of ESRD beneficiaries will actually increase from the present 63,200 to 80,500, and the program expenditures will increase from approximately $1.2 to $2.4 billion. In fact, if one projects on to calendar year 1986, the costs are estimated to be almost $3 billion, and would encompass a beneficiary population of approximately 87,000.

The next chart indicates the types of treatment. [Chart 4 attached.] Since medicare coverage of the ESRD treatment program began, there has been a significant change in the number and proportion of the various types of treatment. As shown here by the black line at the top, 23,281 patients, or roughly almost 90 percent of the total dialysis patients, were dialyzed in in-center facilities in 1976; whereas, by 1980, there was an upward curve to 44,703 patients. This curve represents 85 percent of the total dialysis population who are now receiving in-facility dialysis.

Chart 4



If you notice the lower curve, however, the red line is the line that represents home dialysis, and that line is very important. In 1976, there were roughly 10 percent of the total patients being treated in home. By 1980, the figure had increased only slightly to approximately 15 percent and represents some 7,661 patients.

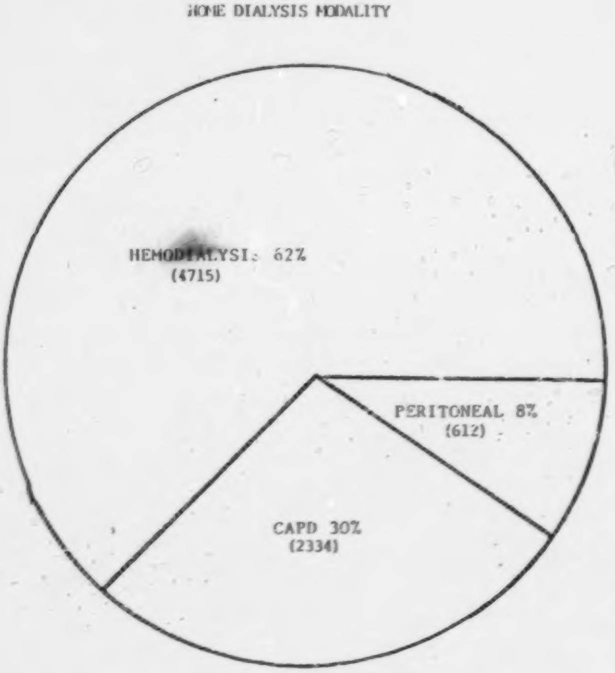
Senator **Durenberger**. Do you have any idea where that red line would be if you went back 6 years?

Dr. **Davis**. Yes, sir. If you go back before the ESRD program began, approximately 40 percent of all patients dialyzing were on home treatment.

Senator **Durenberger**. Thank you.

Dr. **Davis**. Chart 5 indicates that the home dialysis modality has also changed during the period of the program. [Chart 5 attached.] The most recent data for 1980 indicates that roughly two-thirds of the population on home dialysis is receiving hemodialysis treatment, and nearly a third, roughly 30 percent, is receiving a form of treatment called the continuous ambulatory peritoneal dialysis [CAPD]. This particular method, I might add, was only approved for medicare coverage in September 1979. And the growth has been rather significant in that particular treatment. Our latest indications are that for 1981 CAPD will probably be up to about 45 percent.

Chart 5



Also of great significance to us are the data concerning transplants. In 1976, we had roughly 3,175 patients receiving transplants, compared to a small growth of up to 4,697 patients in 1980. However, if we refer back to chart 4 we will see that transplants actually have not kept pace with the overall growth in the population. In fact, the percentage of the patients transplanted in 1980 would really represent a slight decrease of about two-tenths of 1 percent from the percentage of transplants in 1979.

As I stated earlier, one of our most important objectives is to increase the number of home dialysis patients and transplant patients. But to do this we have to seek to reduce some of the barriers that limit the patient access to these modalities.

A few of those barriers are patient disincentives to home dialysis due to the absence of a suitable supporting partner, and inadequate facilities in the home. For example, often the homes lack enough space in which to place the dialysis machine if the patient intends to go on the home hemodialysis treatment. Also, many homes would require extensive plumbing renovations to receive the machinery. In some cases, the volume increase in the electrical and water bills is such that it is a significant cost factor for those who are on home hemodialysis programs.

Another factor is physician attitude. It is a significant factor influencing the patient's choice of a treatment modality. Chronically ill patients tend to have a heavy reliance on their physicians. Therefore, a physician's professional practice patterns will strongly influence referral of the patient to a particular treatment modality. We note, for example, that home dialysis can range from a high of some 45 percent of the total ESRD population in a given region to a low in some other parts of the country of approximately 5 percent.

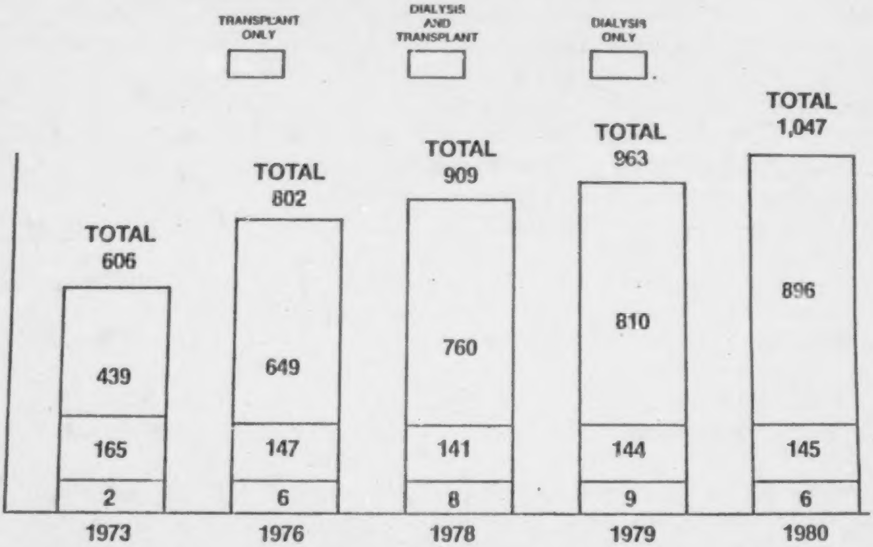
Another factor is education. We believe that both patients' and providers' choices can be influenced by having more data relative to the treatment modality. We are now working to provide such information in the area of mortality and morbidity statistics, and also to update and provide new patient education materials which we anticipate will be available shortly.

There are also some financial disincentives to both physicians and facilities which may provide a deterrent to providing home dialysis. We are now preparing an incentive reimbursement regulation that we think will help to remove those disincentives. If I may, I would like to discuss that at the next hearing.

Another factor which we are aware of is the unavailability of a suitable kidney. It becomes a frequent impediment to transplantation as a treatment option. As I mentioned earlier, there has been a very slow rate of growth in transplants and home dialysis. The next chart indicates that the total facility participation has increased significantly from the establishment of the program until 1980, but most of that growth is due to the dialysis only facility. [Chart 6 attached.]

CHART 6

PARTICIPATING ESRD FACILITIES



Moving on to program management issues—when Congress initially established the ESRD program in 1972, there was hardly any ESRD industry in existence to provide services to this new group of beneficiaries. In the first few years of operation, the program operations were performed primarily through the Social Security Administration, which oversaw the reimbursement and the entitlement functions. Quality assurance activities were administered by the Public Health Service.

Both the quality assurance and the reimbursement functions were brought together in one organization when HCFA was created in 1977. In 1979 a decision was made to centralize the functions and staffs into a single office of end-stage renal disease. That is the particular program structure that I inherited when I arrived at HCFA. However, in studying the activities of the various bureaus and of the activities of the ESRD program, it appeared to me that we could provide a greater degree of management strength, resources, and expertise if we were to have an integrated management structure. I believe that this kind of a realinement, as I have proposed, will effectively utilize the expertise and talents of the individuals in the various bureaus and should give us a stronger management responsibility for the kind of activities that they are involved in.

Currently, it seems to me there has been some duplication of efforts since the reimbursement issues are currently analyzed and discussed in both the office of special programs and in the bureau of program policy. Also, the responsibility for data management has been jointly shared between the office of special programs and the bureau of support services.

The rapidly increasing costs, a growing beneficiary population, the establishment of appropriate reimbursement methods, assuring quality of care, and ascertaining the costs and efficacy of alternative treatment modes are really common not only to the ESRD program but to all of our medicare program areas. I am really quite confident that by using an integrated management structure we can effectively control the programs.

Now I would like to spend just a minute or two discussing networks, our data and research, and then conclude, Mr. Chairman.

As you know, there are 32 ESRD networks covering all geographic areas of the country. The network membership is comprised of a representative of each ESRD facility in the network's geographic area, plus some consumer representatives. The networks are responsible for such functions as encouraging treatment settings to maximize rehabilitation potential and the quality of life; formulating the guidelines for the referral of patients to the most cost-effective and appropriate treatment modalities, and identifying providers who are not complying with national or network goals. I would like to stress that the networks play no role in the reimbursement process or in direct delivery of care.

After nearly 4 years of experience with the networks, we can find little evidence that they have successfully accomplished many of these major functions that I have just mentioned. In looking at the percentage of dialysis patients in the home setting, it appears that they have increased only slightly and that much of this has been due to the recent breakthrough in the use of CAPD and not especially to the efforts of the networks. And, I have already noted that the number of kidney transplants has not appeared to keep pace with the growth in the ESRD population either.

We also feel that we have been disadvantaged with the networks' planning activities. They operate in an advisory capacity regarding the need for new or expanded ESRD facilities. We are concerned that the networks have acted as a franchising board that has limited the entry of new ESRD providers into an area. Moreover, we think that those particular activities would be incompatible with the present administration's procompetitive approach to health care financing.

For these reasons, we proposed the elimination of the ESRD networks in fiscal year 1982. We further believe that the resources to support the networks could more effectively be devoted to the design and implementation of an overall ESRD data collection strategy.

By way of example of what I believe to be the shortcoming of our current data collection activity, I might just mention that we are currently unable to develop reliable estimates on mortality and morbidity of ESRD patients by the type of treatment. At an even more basic level, data are often insufficient or it cannot be arrayed in such a way as to facilitate cost analyses or managerial decisionmaking. We are embarking upon strengthening our activities in this area so that we will have a better data base.

I have also encouraged a substantial increase in our research activities that relate to the ESRD program. Research projects in ESRD focusing on the cost of care in different treatment settings, are being undertaken internally. In addition to our internal studies, we are funding studies on the effects of three treatment modalities—dialysis, transplantation, and CAPD—that will look at the quality of life, the cost of care and the quality of care. We are also examining the effects of competition among ESRD facilities in relationship to the cost of care. Some of our final reports are due in fiscal year 1982 and the remainder of them will be available in fiscal year 1983.

I am also taking a look at the activities that relate to control of fraud and abuse in the ESRD program. We have performed some ad hoc reviews through our program validation efforts to examine the program impact on various ESRD reimbursement issues. I am expecting a report to be issued in January of 1982. The report will provide an evaluation of our current controls and suggested improvements in reimbursement instructions and rules.

While HCFA has played a major role in financing ESRD care, I think it is important to consider that there are several other departmental components, including the National Institutes of Health [NIH], the Center for Disease Control, and the Food and Drug Administration that have ESRD-related responsibilities.

Accordingly, I have recently asked Dr. Jim Donovan of my staff to chair a work group that consists of representatives from the NIH, and the offices of the assistant secretaries for health, public affairs, planning and evaluation, to address some of the issues that I think should be of mutual concern across the Department. These are such areas as dialysis reuse, continued research on the immunosuppression therapy, activities that relate to promoting kidney donations, and to looking at other clinical and technological developments.

In closing, Mr. Chairman, I just want to assure you of my own personal interest in the ESRD program. As the administrator of the agency that spends more resources on end-stage renal disease care than any other in the world, I personally am committed to assuring the success of this program in meeting the needs of the beneficiaries.

This will conclude my prepared statement. I will be happy to answer any questions at this time.

Senator DURENBERGER. Thank you.

Let me start by saying the thoroughness of your statement alone is indication of your commitment.

Obviously, you have a good grasp of the needs, and you feel the same sort of pressures that we do. And I think by your statement you have indicated that you recognize the variety of commonly perceived problems.

Let me ask you some general questions that will perhaps be addressed in some of the testimony we may hear later in the day.

You talked about the integrated management system that you are putting together. One of the things that comes through in all the other testimony is the need for some single identifiable person to appear to be responsible for the overall management of the ESRD program.

Is that appropriate? And, if so, do you intend to appoint such a person?

Dr. DAVIS. I can understand why many of the individuals from the ESRD community are anxious over whom they should talk to. At the same time, I believe that we now have and will continue to have responsible people within the system. It is not that the people are going away. They are going to be integrated into the various bureaus.

The office of professional and scientific affairs will certainly be an office that the professional associations can contact. Likewise, when reimbursement issues are involved, the ESRD community will have no problem in seeking resolution, or at least dialog with the people who work in the bureau of program policy.

Frankly, I would like to hold myself as the one who is accountable rather than isolating accountability in a special program. To my knowledge, I have not failed to meet with any interested group of individuals that have requested a meeting regarding the ESRD program.

Senator DURENBERGER. Are you going to have a complaint department? Of course I do not expect this to be you, but where in this integrated system will physicians and patients deal most routinely? Is your answer that it may depend on the nature of their complaint or their problems?

Dr. DAVIS. Yes, sir. It will depend upon the nature of the complaint.

Also Dr. Donovan, who is an M.D. himself, will be chairing the work group. It will be natural for many of these people to be referred to Dr. Donovan.

Senator DURENBERGER. Let me ask you next about the claims process. Given the low volume of claims for the ESRD program, wouldn't it be better to use a single or at least a regional intermediary to carry your system?

Dr. DAVIS. That is a possibility. It might be better to use a regional intermediary. However, I would not like to use a single nationwide intermediary. I think that geographic differences indicate that this might create some problems for the community itself and the individual facilities.

We are looking at the possibility of recommending regional ESRD intermediaries. We are also aware of the fact that at least we need to have a single source manual with instructions that are unique to the ESRD program. And we are in the process of preparing such a manual which we will then share with the intermediaries and carriers.

Senator DURENBERGER. What is the nature of your relationship or control over the networks? Do you or the Secretary have the authority to abolish the networks?

Dr. DAVIS. I believe that we asked for that as part of our legislative strategy for fiscal year 1982.

Senator DURENBERGER. You don't have it yet?

Dr. DAVIS. No.

Senator DURENBERGER. But it indicates some sense of how you perceive the relative value of the network?

Dr. DAVIS. Yes. I think that in looking over the activities that we felt that the networks should accomplish, there has not been the type of accomplishments, or movement toward the goals that we would like to have seen. In an era when we would have had more resources, we might not have made the determination to suggest that they be eliminated. But, as you well know, with our very significant fiscal constraints, we felt that it was not prudent for us to continue to support their use.

Senator **DURENBERGER**. Your statement about the networks seem to indicate that theirs was, in large part, the utilization role, and you were disappointed in how they carried out that role.

Do you see utilization as having been their primary responsibility? And to what extent have factors like reimbursement affected the utilization of dialysis services?

Dr. **DAVIS**. I would not say that reimbursement has not had some effect on it. I believe that it has. However, I think that if you look at the significant differences in the networks between the percentage of individuals who are on home dialysis—and they do vary, as I indicated from a high of 45 percent in, say, the Washington network area, to a low in several areas of 5 to 6 percent—I have to believe that these differences could be influenced by the networks since the networks are representative of the dialysis facilities.

Senator **DURENBERGER**. Have you looked at using PSRO's as an alternative, either in utilization or quality control?

Dr. **DAVIS**. No, sir, we have not. Since the administration had recommended that we phase out PSRO's, they have not been a mechanism we have looked at.

Senator **DURENBERGER**. Would you be willing to look at PSRO's now that we have temporarily persuaded the administration of their value? [Laughter.]

Dr. **DAVIS**. I think it would be prudent for us to take a look to see whether or not any of those activities could be successful.

Senator **DURENBERGER**. I am going to have to leave and Senator Baucus should be back momentarily. So if it doesn't inconvenience you too much, I will just recess the hearing very briefly until he returns. Thank you very much.

Dr. **DAVIS**. Thank you, sir.

[Whereupon, at 2:30 p.m., the hearing was recessed.]

AFTER RECESS

Senator **BAUCUS**. Senator Durenberger should be back I suspect in about 5, 6, or 8 minutes when the vote is over. Meanwhile, I might as well for sake of time continue the hearing.

Miss Davis, I don't know the degree to which Senator Durenberger got into this, but I wonder if you could tell me what efforts are being made in your behalf and others to try to encourage more people who are on dialysis to move to their homes rather than institutions, hospitals, centers and so forth?

I understand that the proportion, the percentage of people, who are on home renal dialysis has really declined generally in the last several years, but I guess there has been a slight increase in percentage just in the recent period of time. But if you could just tell me more specifically what efforts you or others might be making and the propriety to which you should gage that effort.

Dr. **DAVIS**. Yes. I am sorry, Senator.

Senator **BAUCUS**. And also the propriety of that effort.

Dr. **DAVIS**. Oh.

Senator **BAUCUS**. That is, the appropriateness, not corrected.

Dr. **DAVIS**. Right.

Yes, it is true that before the medicare program came into existence, some 40 percent of the patients were being dialyzed at home. Since the funding of the dialysis program by medicare, we have seen a significant decrease so that at one point home dialysis patients constituted a low of approximately 10 percent of the total ESRD patients. They are now up to approximately 15 percent.

We believe that a great deal of that growth has been due to the payment for a new treatment modality beginning in 1979 when medicare recognized the appropriateness of paying for continuous ambulatory peritoneal dialysis, CAPD, as an effective home dialysis treatment program. There has been a significant increase in the number of individuals who are now being dialyzed under that particular methodology.

At this time, I do not think it is appropriate for us to make a judgment call as to which modality is best. What I think is an appropriate approach for the Health Care Financing Administration is to provide the data and the information to make sure that the patients and providers have a data base so that they can make their own choices in terms of what is the best method for the particular patient involved.

Senator BAUCUS. But as administrator of the program, don't you think it would be a good idea if your office also knew the degree to which, based upon medical judgment at your disposal, that some patients could indeed move to home care rather than having their care via the institutions? I mean, it seems to me, as administrator of the program, even though you would not be making the specific recommendation per patient, at least as a general rule it might be helpful.

Dr. DAVIS. Yes. There will be in the new rate settings that we will be suggesting shortly an incentive mechanism for home dialysis programs. But in terms of making the actual determination, we think that is a physician judgment call.

Senator BAUCUS. I don't think I understand you. You say you will sometime be in a position——

Dr. DAVIS. We are about to promulgate new regulations that address an incentive reimbursement rate for home dialysis programs.

Senator BAUCUS. Will you be in a position to know, based upon your best judgment, whether all patients should move to home dialysis at some time as a general principle?

Dr. DAVIS. I am not certain that we could make a judgment call as to whether more should move to a home dialysis program or not. Again, I think that is a medical judgment.

One fact I would point out is that while 40 percent of the patients were on home dialysis prior to the advent of medicare coverage in 1973, the patient population that was being dialyzed was also different at that point. That was a younger population.

If you look at the social characteristics of the groups that were being dialyzed, from 1967 to 1973 when the medicare coverage began, and contrast that to the present population, one notices that the current population is older. In 1978, 47 percent of the patients were over the age of 55. That was a significant difference from former days when they dialyzed only a very young patient population. To the degree that the population is older, and it may have more serious difficulties, such as diabetes——

Senator BAUCUS. I am asking these questions because I personally believe that the kind of information, at least an inflection of more data, at least enable you to be in a better position to make recommendations to the Congress as to what changes, if any, we should make in the program.

Dr. DAVIS. Well I think we are after a better data base than we have had, and we are looking at the data. While you were out, Senator, I was mentioning that one of our research projects is looking at the various treatment modalities, trying to get some cost data and some quality of life data, and we anticipate that that material will be ready in early 1983.

Senator BAUCUS. 1983? Are we still going to be here?

Dr. DAVIS. I hope to be. [Laughter.]

Senator BAUCUS. Why does it take that long? And I say that because usually when someone makes an estimate, it takes longer.

Dr. DAVIS. We have been under a rather intensive scrutiny in terms of our research program activities. We have tried to look at tightening up all of the kinds of activities that we could. What we have really tried to do is to make a profile. There is a great deal of data that is available but it has not been available in a usable format. The data is somewhere. We have to aggregate it and then do an analysis of it and evaluate that. It is that kind of data in terms of the three modes of treatment—hemodialysis, transplantation, and CAPD—that we will be examining and studying.

Senator BAUCUS. We will temporarily recess. By temporarily I mean like 15 seconds. Senator Durenberger is on the telephone.

[Whereupon, at 2:39 p.m., the hearing was recessed.]

AFTER RECESS

Senator BAUCUS. Could you more precisely tell me why it takes so long? What are some of the mechanic problems that you have? Would you outline that a little bit? Frankly, on the face of it, I seem to think that we can speed that data up a little bit earlier with a little bit of effort. If you need help on our behalf, that could be arranged.

Dr. DAVIS. In terms of that particular study that I was referring to, you have to pick your sample first. Although that sounds simple, you have to aggregate your material and then analyze that. Then you go about the process of interviewing, because part of the determination of the quality, as well as the methodology, has to deal with direct interviews with some of the patients to determine what they perceive their concerns to be. So interviewing takes a great length of time; then there is the analysis of the interviews. And at the same time we are collecting aggregate cost data. Most people who are into large research activities like this would consider that a 3-year timespan is not that lengthy, Senator.

Senator BAUCUS. What about data collections, generally? What are you doing to help address that problem?

Dr. DAVIS. I am sorry, sir.

Senator BAUCUS. Data collections, generally.

Dr. DAVIS. We have just instituted a new data collection system which will be monitored through our Bureau of Support Services.

Our data has not been good. We recognize the fact that we have had an immense amount of data that has not been easily aggregated and utilized, as I indicated earlier. We are working hard to try to pull together our medical information system so that it can provide a better data base for us internally.

Senator **Baucus**. Why is it that the data thus far has not been useful?

Dr. **Davis**. Until about 1 year ago we had difficulty getting the data from all of the facilities. In the last year the facilities have been very good in terms of——

Senator **Baucus**. Why? Are they just slow or just don't like to provide the data? Or what is the problem?

Dr. **Davis**. They simply did not return the forms. And we had no real authority to enforce the return of the forms.

In terms of asking for the data, we would send out a questionnaire. And if they did not choose to return it, they did not return it.

In the last year, there has been minimal improvement in compliance with the patient-specific medical information forms. However, we have had very good compliance with the facility aggregate treatment survey. So we are now beginning to build a better data base than we have done in the past.

Senator **Baucus**. So you are saying centers now do provide the data?

Dr. **Davis**. I beg your pardon.

Senator **Baucus**. You are saying now that the dialysis centers now do provide the data very quickly?

Dr. **Davis**. They provide the aggregate statistics timely; however, we continue to have a compliance problem with patient-specific medical information.

Senator **Baucus**. They were just resistant? Why the change of heart? What happened, if anything?

Dr. **Davis**. We had asked for authority for reimbursement sanctions in our proposed legislation. That may have had something to do with it.

Senator **Baucus**. It is my understanding that this committee asked for this data in 1978. Are you aware of that?

Dr. **Davis**. I was not here then, but I do understand that in the amendments there were requirements for data.

Senator **Baucus**. No; I know you were not here. But I was wondering whether the Department informed you of that request.

Dr. **Davis**. Senator Baucus, when I came into this job I began to look very deeply into the activities that related to the ESRD program, and was very concerned over the fact that we did not have the data in place, either for cost or for the medical information system.

In the last 6 months that I have been aboard we have been trying to get that straightened out, and I think we are on the right track now. I cannot answer to what the previous administration did or did not do in terms of collecting that data.

Senator **Baucus**. I am sure I can speak for Senator Durenberger, but obviously they wanted sufficient data collection processed. And this administration generally stands for efficiency, and I am, therefore, looking forward to more efficiency. [Laughter.]

And if you need some help, I stand here ready to help you out, and Senator Durenberger does as well, because obviously there have been a lot of delays and that has not been very helpful. And I am sure that this kind of discussion occurred years past several times. And none of us like to waste our time. So I just suggest a little effort and imagination on your part as well as ours so that we can perhaps avoid the same discussion a year or two from now and particularly in 1983.

Dr. **Davis**. I can assure you we will not have this type of discussion then, Senator Baucus. We will have the data.

Senator **Baucus**. Thank you. I have probably heard those assurances, too, but we will see. Thank you.

Senator **Durenberger**. For the sake of efficiency, I will pass up the balance of my questioning. Thank you very much, Dr. Davis, for your presentation. And, gentlemen, thank you.

[The prepared statement of Carolyne K. Davis follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Washington, D.C. 20201

STATEMENT BY

CAROLYNE K. DAVIS, PH.D.

ADMINISTRATOR

HEALTH CARE FINANCING ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON FINANCE

UNITED STATES SENATE

SEPTMBER 28, 1981

SUMMARY

- THE MISSION OF THE END STAGE RENAL DISEASE PROGRAM IS TO ASSURE THAT PATIENTS WITH END STAGE RENAL DISEASE HAVE ACCESS TO HIGH QUALITY, COST EFFECTIVE MEDICAL CARE.

- HCFA HAS ESTABLISHED A NUMBER OF GOALS TO CARRY OUT THIS MISSION. ONE IMPORTANT OBJECTIVE IS TO INCREASE THE NUMBER OF HOME DIALYSIS PATIENTS AND TRANSPLANT PATIENTS.

- SINCE THE PROGRAM BEGAN THERE HAS BEEN A STEADY GROWTH IN THE NUMBER OF BENEFICIARIES AND PROGRAM COSTS.

- I AM PROPOSING TO REALIGN ESRD FUNCTIONS WITH THE OVERALL MEDICARE PROGRAM STRUCTURE. AN INTEGRATED PROGRAM MANAGEMENT STRUCTURE WILL BRING GREATER MANAGEMENT STRENGTH, EXPERTISE AND RESOURCES TO BEAR ON THE PROGRAM.

- WE HAVE BEEN DISAPPOINTED WITH NETWORK PERFORMANCE AND PROPOSED THEIR ELIMINATION.

- MANAGEMENT EFFORTS ARE ALREADY UNDERWAY IN THE AREAS OF ESRD DATA COLLECTION, RESEARCH, AND FRAUD AND ABUSE. HCFA IS COORDINATING ITS ACTIVITIES WITH OTHER DEPARTMENTAL COMPONENTS.

Mr. Chairman, I am Carolyne K. Davis, the Administrator of the Health Care Financing Administration (HCFA). With me today are Dr. James P. Donovan, Associate Administrator for Management and Support Services (HCFA), and Mr. Spencer Schron, Director, Office of End-Stage Renal Disease (HCFA).

Introduction

We are pleased to be with you to discuss the Medicare End-Stage Renal Disease Program. As you requested, I will discuss the operations and management of the program today. I understand that reimbursement issues will be the subject of your subsequent hearing.

Eight years have gone by since Congress authorized the End-Stage Renal Disease (ESRD) program. In passing the legislation, Congress stated the program's mission: to assure that patients with end-stage renal disease have access to high quality, cost-effective medical care. In keeping with this Congressional intent, HCFA has established the following goals and objectives for the program:

- To ensure that beneficiaries who have been diagnosed as having end-stage renal disease receive the care they need;
- To encourage proper distribution and effective utilization of ESRD treatment resources while maintaining or improving the quality of care;

- To provide for the efficient delivery of appropriate care by physicians and facilities; and
- To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatments.

Growth of ESRD Program

To place the operation of the program in perspective, I believe it will be helpful to outline the growth of the program since its inception.

Beneficiaries

My first chart traces the growth of the program from 1974 (the first full year of operation) to 1980. As this chart shows, in 1974 there were 18,412 renal beneficiaries. The number of beneficiaries steadily increased year-by-year, with an average annual rate of increase of about 40 percent. By the end of 1980 there were 63,214 beneficiaries, approximately 3-1/2 times the original number.

I should point out that these Medicare beneficiaries account for approximately 93% of all patients with irreversible kidney failure. The ESRD program requirements for Medicare eligibility are quite broad, and virtually the entire population of dialysis and transplant patients is covered under the program.

Cost

This dramatic increase in the growth of beneficiaries, is, of course, one of the major factors that accounts for the significant increase in the cost of the renal program. Program expenditures grew from $228.5 million in 1974, the first full year of operation, to about $1.2 billion in 1980.

In addition to the increase in beneficiaries, the high cost of treatment is a major factor in the large cost of the program. In 1980, the average cost per dialysis session was $137.49, (excluding physician fees) and these patients are dialyzed on an average of 3 times per week. This results in an annual costs of $21,500. Moreover, when a dialysis patient becomes entitled to Medicare benefits, the dialysis treatments and their costs continue until he is transplanted or dies. There is little prospect of terminating the benefits through a cure.

For transplant patients, the average cost in 1980 for a transplant operation was $20,156(again excluding physician fees) . Moreover, after a patient receives a transplant his benefits continue for 3 more years. During this time, costs are incurred for the continuing treatment aimed at preventing rejection of the new kidney. Of course, this assumes that this continuing treatment is successful. Unfortunately, many transplanted kidneys are rejected. According to the American Society of Transplant Surgeons, there is a 20-25% failure rate for transplants involving a living related donor at 2 years, and a 30-43% failure rate at 2 years for cadaveric grafts. This means that these patients must be returned to dialysis and possibly receive a new transplant later. Nevertheless, we still believe that transplantation is a more economical procedure than hemodialysis, and it offers patients a higher quality of life than does dialysis.

As a result of this high cost of renal treatment there has been a dramatic increase in the average cost per ESRD patient. Chart 2 shows that in 1974 the cost per renal patient was $11,163. This per capita cost increased to $18,888 in 1980, representing an increase of 69 percent over the 1974 figure. Much of this increase represents the impact of inflation in health care costs in general. In fact, this 69 percent rate of increase per ESRD patient is less than the comparable rate for the other Medicare beneficiaries. By way of comparison, the rate of increase in expenditure per non-ESRD Medicare beneficiary is 114 percent over the 1974-1979 period.

We can gain further appreciation of the high cost of the ESRD program from the fact that the renal beneficiaries represent less than one-quarter of one percent of all Medicare beneficiaries. Yet this one-quarter of one percent accounts for about 10 percent of all Medicare Part B reimbursement and just over one percent of Part A. Moreover, future projections point to even more substantial program costs. HCFA's actuaries estimate that by 1984 the number of ESRD beneficiaries will increase from the present 63,200 to 80,500, and program cost will increase from the present approximately $1.2 billion to almost $2.4 billion.

This projected escalation in ESRD expenditure points out HCFA's task. The increase in costs that is attributable to the increase in beneficiaries, of course, can not be controlled. However, where cost increases can be controlled by good program management, we must look for administrative measures that will be cost-effective. I assure you that we intend to do so.

Types of Treatment

Since Medicare coverage of ESRD treatments began, there has also been a change in the numbers and proportions of the various types of treatment received by beneficiaries. As shown on Chart 3, in 1976, 23,281 patients (89.8

percent of the total dialysis patients were dialyzed in facilities). The 1976 in-facility dialysis patients included 22,870 hemodialysis patients (98.2 percent of the total) and 411 peritoneal dialysis patients (1.8 percent of the total). By 1980, 44,703 patients (85.4%) of the total dialysis population received in-facility dialysis, including 43,641 patients (97.6 percent of the total) who received hemodialysis and 1,062 patients (2.4 percent of the total) who received peritoneal dialysis.

The data on this chart relating to home dialysis are very important. In 1976, 3,486 patients (10.2 percent) received dialysis in their homes. In 1980, this figure has increased to 7,661 patients (14.6 percent).

A rapidly growing component of home dialysis is Continuous Ambulatory Peritoneal Dialysis (CAPD). In 1973, this type of treatment did not exist, except on an experimental basis. CAPD was not medically approved for Medicare coverage until September 1979. In that first partial year only 465 patients (1.0 percent) received CAPD. In 1980, 2,334 patients (4.5 percent) received CAPD.

Also of great significance to us are the data concerning transplants. In 1976, 3,175 patients received transplants, compared to 4,697 patients in 1980. As I stated earlier, one of our most important objectives is to increase the number of home dialysis patients and transplant patients. To do so, we will have to seek to reduce some of the barriers that limit patient access to these modalities. These barriers include:

1) Patient Disincentives - With respect to home dialysis, the absence of a suitable supporting partner and inadequate facilities in the home are often barriers. For example many homes lack enough space in which to place a dialysis machine. Also many patients are unable to make the extensive plumbing renovations that the machine requires.

2) Physician Attitudes - A significant factor influencing patient choice of a treatment modality is physician attitude. Chronically ill patients tend to have a heavy reliance on their physicians. Therefore, a physician's professional practice patterns will strongly influence referral to a particular treatment modality.

3) Education - Access to information, by physicians, staff and patients, on the various

treatment modalities, including general information and mortality/morbidity data influence patient choice. HCFA is now working to increase the availability of such information, particularly mortality/morbidity statistics. Also, several patient education materials have been recently developed by HCFA and will be made available shortly.

4) Financial Incentives/Disincentives - Financial disincentives to physicians and facilities may exist for providing home dialysis and continuous ambulatory peritoneal dialysis (CAPD). In accordance with a provision of the "Omnibus Budget Reconciliation Act of 1981" (P.L. 97-35), HCFA is preparing to issue incentive reimbursement regulations that will help to remove these disincentives. Some of these issues will be discussed in the subsequent hearing.

5) Availability of Kidneys - The unavailability of a suitable kidney is a frequent impediment to transplantation as a treatment option. Several factors are critical to assure a successful match between a cadaveric kidney and a potential transplant recipient. One of the key factors is tissue typing. Most transplant surgeons require at least a 3 antigen

match. A second key factor is timing. The cadaveric kidney must be speedily transplanted to assure a greater chance of success.

Also, kidney registries which list available kidneys are not adequate in all areas of the country and, as a result, patient access to transplants is affected. HCFA has been working closely with the agencies which maintain the registries to eliminate this problem. Transplant hospitals report that they have a backlog of 4,825 dialysis patients on their transplant registries. Dialysis facilities report 1,541 patients on transplant registries. Also, HCFA has funded a study to identify the factors which make organ procurement agencies successful. We expect that findings from this study will guide us to assess the strategy that makes some of these agencies effective in obtaining and distributing kidneys. We can then develop recommendations to influence all of these agencies to adopt a successful strategy.

I believe that this information demonstrates both the growth and the complexity of the ESRD program. I will now turn to program management issues.

Program Management

The Committee has raised concerns about program operations that fall into the major areas of:

- overall program management, including the role of the networks and identification and prevention of abuse;
- program data and research; and
- quality of care.

Many of these concerns undoubtedly stem from the attention that has been focused on program costs, which have outstripped most projections made at the outset of the ESRD program. It might be assumed that program management will focus on costs at the expense of quality and accessibility of care. Let me assure you that this is not to be the case.

When Congress established the ESRD program in 1972, there was hardly an ESRD industry in existence to provide services to this new group of beneficiaries. With less than a year between enactment of the legislation and the date when new beneficiaries were to become eligible for Medicare in 1973, the program was structured along the same lines as the Medicare program. The Social Security Administration performed or oversaw most entitlement and reimbursement functions, and quality assurance activities were administered by the Public Health Service. Management resources were devoted to putting into place: (1) the reimbursement incentives that would attract providers into this new service area, (2) the standards and certification measures necessary to assure quality of care, and (3) the operational components and mechanisms for making entitlement determinations and paying the bills.

The quality assurance and reimbursement functions were brought together in one organization with the creation of HCFA in 1977. By this time, the ESRD program had escalated in both size and costs beyond the early projections, and it became increasingly clear that the management agenda would likewise have to shift to address concerns related to efficiency and cost-effectiveness in the organization and delivery of care. In 1979, the program's operational functions and staffs were consolidated into a single Office of End-Stage Renal Disease.

This is the program structure I inherited upon my arrival at HCFA. I believe, however, that greater management strength, resources and expertise can be brought to bear on the program through an integrated management structure. Such a structure as I have proposed will realign ESRD operations so that they are once more integrated with those HCFA components that have functional responsibility for similar activities in the overall Medicare program.

Rapidly increasing costs, a growing beneficiary population, establishment of appropriate reimbursement methods, assuring quality of care, and ascertaining the costs and efficacy of alternative treatment modes are common not only to the ESRD program and the rest of the Medicare program but to all consumers, providers and payors of health care today.

Networks

I would now like to talk about the appropriate role and responsibility of the networks. As you know, there are 32 ESRD networks covering all geographic areas of the country. Network membership is comprised of a representative of each ESRD facility in the network's geographic area, plus consumer representatives.

As specified in legislation and regulations, the networks are responsible for:

- encouraging treatment settings to maximize rehabilitation potential and quality of life;
- developing guidelines and standards for quality patient care;
- formulating guidelines for the referral of patients to the most cost-effective and appropriate treatment modalities;

- identifying providers not complying with national/network goals; and
- contributing data on ESRD facilities and patients for inclusion in the annual report to Congress.

The networks play no role in the reimbursement process or in direct delivery of care.

After nearly four years of experience, we find little evidence that the networks have successfully accomplished any of their major functions. While the percentage of dialysis patients in a home setting has increased, much of this increase appears to reflect the growing use of CAPD and not the efforts of the networks. The number of kidney transplants has not kept pace with the growth of the ESRD population. Few networks have had any impact on quality of care, having focused attention largely on hepatitis prevention and water standards rather than more difficult or controversial issues such as mortality rates, rehabilitation status, and kidney graft outcome.

We have also been dissatisfied with the networks' planning activities. In their advisory capacity regarding need for new or expanded ESRD facilities, we are concerned that the networks have acted as franchising boards that have limited the entry of new ESRD providers into an area. These activities are incompatible with the Administration's pro-competitive approach to health care financing.

For these reasons, the Administration proposed elimination of the ESRD networks in FY 1982. In addition, we believe the resources used to support networks could more effectively be devoted to the design and implementation of an overall ESRD data collection strategy.

Data

The existing ESRD data system has ill-served both program managers and the research community. Because much of the data we routinely collect is inadequate for the purpose for which it has been collected, we have had to undertake special purpose data collection activities or to delay initiating studies on ESRD program operations. As a result, the program too often appears non-responsive to requests for basic program information. As examples of the shortcomings of current data collection activities, HCFA is unable to develop reliable estimates of mortality and morbidity of ESRD patients by type of treatment. At an even more basic level, data are often either insufficient or cannot be arrayed to facilitate cost analyses or managerial decision making.

Research

I have encouraged a substantial increase in research activity on the End-Stage Renal Disease Program. Work is ongoing in the studies mandated under the ESRD Amendments of 1978 (P.L. 95-292) for which HCFA has the lead responsibility. Research projects in ESRD focusing on the costs of care in different treatment settings are being undertaken internally. In addition, we are funding studies on the effects of three treatment modalities (dialysis, transplantation and CAPD) on the quality of life, quality of care and cost of care. We are also examining the effect of competition among ESRD facilities on the cost of care. Final reports from these studies will be available in 1983.

Fraud and Abuse

We are also concerned about adequate controls over fraud and abuse in ESRD. The fraud and abuse control activities are now integrated into the Medicare contractors' regular claims and audit process. This process involves computer screens on a prepayment and post-payment basis to ensure the appropriateness of the ESRD payment. Audits are performed where there is cost-based reimbursement (hospital-based facilities) to verify the accuracy of reported costs. The regional offices provide oversight of these contractor claims payment and audit processes to evaluate and ensure the integrity of these systems. In addition, HCFA has performed ad hoc reviews through program validations to examine the program impact of various ESRD reimbursement areas. (The on-site portion of these reviews is nearly complete and I am expecting a report to be issued no later than January, 1982, which will provide an evaluation of current controls and any needed improvements.)

Future Strategy

From a management perspective, I am committed to overcoming many of the problems that have plagued this program since its inception. While HCFA plays the major role in financing ESRD care, it is important to consider that several Departmental components - including the National Institutes of Health, the Center for Disease Control, and the Food and Drug Administration - have ESRD-related responsibilities. Accordingly, I have asked Dr. Donovan of my staff to chair a work group consisting of representatives of the National Institutes of Health and the Offices of the Assistant Secretaries for Health, Public Affairs, and Planning and Evaluation to address issues of mutual concern, such as:

- dialyzer re-use,
- research on immunosuppression therapy,

- promoting kidney donation, and
- other clinical and technological developments.

In addition, I am concerned that HCFA begin to examine more fully the comparative rehabilitation potential for ESRD patients in different treatment modes. In the past, we have observed that higher rates of return to work or other productive activities among patients are associated with certain tretment modalities, most notably transplantation and home dialysis. (CAPD may demonstrate similar potential, although it has been too recently introduced to assess.) We certainly plan to further investigate these relationships so that we might take this rehabilitative aspect of patients' needs into account as we structure future ESRD policy.

Finally, I would like to take a moment to assure you that my interest in the ESRD program is not fleeting. In the short while that I have been with HCFA, I have met regularly with members of the renal community. As I noted earlier, the ESRD program consumes about 10 percent of total outlays under Part B of Medicare. I devote at least a comparable share of my time to ESRD issues. As Administrator of the agency that spends more resources on end-stage renal disease care than any other in the world, I am personally committed to assuring the success of this program in meeting the needs of its beneficiaries.

Senator DURENBERGER. Our next witness will be Dr. Richard Rettig. He comes to us from the department of social sciences, Illinois Institute of Technology, Chicago, Ill., and is at least one of the authors of a major report on this problem. And we appreciate your taking your time to be here with us today, Dr. Rettig, and acknowledge your familiarity with the subject, not necessarily your expertise in every single aspect of it. We are indebted to you for taking your time to share your thoughts with us today.

STATEMENT OF DR. RICHARD RETTIG, PROFESSOR OF SOCIAL SCIENCES; CHAIRMAN, DEPARTMENT OF SOCIAL SCIENCES, ILLINOIS INSTITUTE OF TECHNOLOGY, CHICAGO, ILL.

Dr. RETTIG. Thank you very much, Senator.

My name is Richard Rettig. I am professor of social science at Illinois Institute of Technology. I was recently with the Rand Corp., and it was there that I did the research resulting in the report on the end-stage renal disease [ESRD] program that you have.

Since today's hearing deals with program operations and management, I will emphasize those things which are pertinent to organizational questions in the broad sense.

First, I would like to begin by stressing the special nature of the ESRD program that makes it different from the normal medicare program in certain distinctive ways.

The program reimburses lifesaving treatment by dialysis and transplantation, treatments that resulted from the Federal Government's investment in medical research. Second, patients are treated on a continuing basis, and that is the basic element driving the costs. No immediate prospects are on the horizon for significant new treatment or preventive capabilities. So this program and its associated cost burden in something roughly like its present form is apt to be with us for another decade or so.

Futhermore, there now exists a growing number of individuals whose lives are sustained by dialysis and transplantation and a very highly trained, articulate cadre of physicians and surgeons who treat these patients. The beneficiaries and their agents are thus clearly identified and highly articulate and predictively will bring their demands to the Government. This is very important from an administrative standpoint.

Finally, the most distinctive feature is that the market for end-stage renal disease, as was recognized in 1973, is a Government-made market, and, thus, unlike the general medicare program with its parallel nonmedicare market. So the behavior of patients, physicians, and provider institutions takes place within the constraints and incentives that are established almost exclusively by Federal policy.

These features give the program its special character and insure that it will impose a special administrative load on the Health Care Financing Administration.

It is useful to remember that the ESRD program is special in another way. That is, no one thinks that our scientific, technological, and clinical prowess in developing lifesaving treatments will end with dialysis and transplantation. On the horizon are heart transplants, artificial hearts, and other therapies. It behooves us to learn from this experience to the greatest extent we can so that the Congress, the executive branch, and the public can more effectively grapple with similiar situations that arise in the future.

Let me not address the current HCFA reorganization since I am not familiar with what is being proposed; rather, let me comment on those organizational capabilities that are needed to administer this program.

First, in my view, it is useful and necessary for the Secretary to designate a single individual in his office to essentially carry the ESRD portfolio, to be the focal contact point, and to convene the relevant officials within the Secretary's Office, and be the focal point of interaction between the Office of the Secretary and the Health Care Financing Administration.

Second, within the Health Care Financing Administration itself there should be a single individual responsible to the Administrator and the Deputy on ESRD matters and a focal point of coordination. If there is no one short of the Administrator who is in charge, there is no one short of the Administrator who is in charge.

Under those circumstances, things either come always to the Administrator or they are administered in a fragmented way. We will once again have the familiar situation of mastering the division of labor without mastering coordination.

A second element needed is a strong reimbursement policy capability. Such a capability existed up until 1977 or 1978. Then, a combination of retirement, reassignment, and the general reorganization caused by the creation of HCFA, essentially decimated that capability. Within a few months, new legislation was enacted, in 1978, and this legislation generated the need to rebuild that reimbursement policy capability. It is that decimation and rebuilding experience which is part of the reason for the delay in the issuing of the incentive reimbursement regulations that were called for in that 1978 legislation.

Another thing that is needed is a strong cost-analysis group. This program could insure itself much less grief if, on a continuing basis, it generated a series of both substantial and small discrete cost studies on various aspects of the program. This should be an internal cost-analysis capability.

A related need is for a strong internal medical data acquisition and analysis group. Now the program may have weathered some storms and be on its way to better performance, but it has yet to demonstrate the capacity to acquire a minimal amount of high quality descriptive data in a regular way. That is what is needed. I think the classic comment was that of deputy editor of the New England Journal of Medicine about the ESRD program's second annual report: "Twenty-seven pages of data on transplantation and nothing on survival."

Now our expectations about the effective and efficient administration of Government programs assume that we can learn from experience. Without the data that reflects that experience, the Government is captive of external interests and is like a ship without a rudder. Both cost analysis and medical information data capabilities are needed.

Finally, a strong operations capability is needed to monitor any exceptions process established for reimbursement purposes. In fact, the weakness of the exceptions review capability caused us to drift to the de facto, two-tier reimbursement system for free standing facilities, and hospitals for outpatient treatment. A strong operations group is an important investment to make.

This brings me to networks on which I will comment very briefly. First, networks consume a large portion of HCFA administrative resources, resources that might be usefully addressed to other purposes.

Second, they have extremely limited capabilities. They contribute nothing to increased patient access to treatment. They contribute nothing to cost control. They basically represent provider interests and only minimally represent patient interests.

They cannot resolve conflicts among physicians and provider institutions unless there is a predisposition to cooperation that exists independently of the networks. And networks have, on occasion, been used to limit the entry of new treatment facilities, primarily for reasons of the financial interest of previously certified facilities.

Most seriously, networks cannot demonstrate a measurable beneficial effect on patient well-being due to inadequate data, inadequate measures, infrequency of measurement, reliance on records rather than direct observation, and the concurrent operation of more important factors.

Given these limitations, networks should either be eliminated or modified to perform functions they can achieve. In particular, they now collect data, a purpose for which they were not originally intended but for which they might be well suited.

You raised several questions that I have grouped under the question, should ESRD facilities be certified? You have asked about the functions of network in the facilities certification process, the certificate-of-need requirements of health planning, the annual facility survey and recertification process. These are all manifestations of a policy adopted in 1973 which froze existing treatment capacity, and then later relaxed that constraint to let capacity grow in relation to patient population growth.

That policy was predicated on the assumption that it was desirable to avoid overbedding in the dialysis field and on the belief that the dialysis situation was analogous to the hospital overbedding problem that medicare then confronted. In fact, when medicare introduced the reimbursement screen, it created a powerful incentive to facilities to fully utilize existing capacity and avoid creating excess capacity.

So, in important ways, that original policy of limiting capacity to insure adequate utilization was superfluous relative to the incentives that reimbursement policy established.

The point is that Congress and the administration are not dealing with certificate of need or an annual survey process, but with the basic policy that has governed the program since 1973.

Under these circumstances, it is now being suggested that the system might be deregulated and that relations among providers and facilities be made more competitive. That may be an appropriate policy to pursue. But some caveats are needed at this juncture relative to such a proposed course of action.

First, the comprehensive analysis of what a procompetition policy might entail has yet to be performed. This would necessarily include not just static economic analysis, but analysis of the legal, institutional, and clinical implications in a dynamic context, both for the short term and the long term.

Assuming one can posit an ideal competitive situation, great attention then has to be given to the transaction costs of getting from here to there.

Third, in terms of the policy process, it would be useful to have a specific proposal for discussion. To the extent the committee is interested in a competition course, it might ask its staff to generate that kind of a proposal and then subject that proposal to the scrutiny of the hearing process.

In a word, Dr. Enthoven has yet to write the adaptation of "Health Plan" for the ESRD program.

I would say, going on to another point, that one thing to be done is to strengthen the representation of patient interests. This is entirely consistent, if you please, with a procompetition policy.

I want to suggest a cost study, going on to the final point, that moves away from the conceptually flawed analysis of the relative efficiency of different institutions administering part B funds to a more comprehensive approach. It should be possible to draw three patient samples, those patients primarily treated in the hospital, those in freestanding facilities, and those treated in the home setting. Then one could examine both part A and part B expenditures, and coinsurance expenditures, and monthly disability expenditures from title II and title XVI of social security. I would guess—this is not an estimate—I would guess that those disability expenditures, in addition to medicare, run in the neighborhood of $100 to $250 million for the medicare ESRD beneficiaries.

This type of study would give a more discriminating view of the total cost to the Government of the program we are undertaking, not just the medicare cost.

Finally, I will conclude by restating the point I made earlier. The ESRD market is a Government-made market. There is no natural market for these services. Without medicare, we would be back where we were before 1973. Any set of incentives that move toward a procompetition policy are going to derive directly from Federal Government policy, and so should be approached with great thought, and prudence, and great attention of the specifics of the proposal.

Thank you for the invitation to appear here. I am happy to be of any further help to you.

Senator DURENBERGER. Thank you very much for your presentation.

Let me ask you, if the medicare had not come along with the end stage renal disease program, what do you think the provider system would look like today?

Dr. RETTIG. A patchwork similar to what you had in 1972 or early 1973, some Public Health Service moneys, the Veterans' Administration, some State governments, some use of Federal/State funds, some private resources.

Senator DURENBERGER. That is the financing. But what about the provision of services? Where would people be receiving their dialysis?

Dr. Rettig. Substantially greater reliance upon home dialysis. That much is clear. That England, Australia, New Zealand, this country under resource constraints put people in the home setting because the dollars were not available.

The people who initiated national medical care were themselves engaged in home dialysis in the late sixties and early seventies for a very explicit reason. There was no money to do anything else.

It is also true that providers would be rationing care. There are people who are sicker today and older today in the patient population who would have died earlier, would not have had access, and we would revert to that same situation today.

Senator Durenberger. Over the last 8 years, what have our achievements been with respect to quality?

Dr Rettig. It is my impression, and the physicians and patients can speak more effectively than I, that the quality of care is reasonably good because there exists a highly trained group of physicians, a highly concerned set of medical professionals and patients whose lives depend upon treatment. These patients are thus somewhat less tolerant of poor quality than you and I when treated for an acute illness episode.

I think these are some natural reasons to think that quality of care is reasonably good but have not measured that quality of care and, indeed, I don't think we can measure that on a recurring basis.

Senator Durenberger. You started out advocating a single-person theory, and I think you then ended up recommending two single people, one in the Office of the Secretary and another one working for Dr. Davis.

You were here for the testimony of Dr. Davis. Would you characterize her testimony as a well-intentioned effort to give some direction, but that perhaps she is taking on too much?

Dr. Rettig. I don't understand, from the testimony, precisely the nature of the proposal that is being advanced. It apparently would not have a single person responsible for the program.

My apprehension, based on knowledge of bureaucracies, is that under those circumstances, either everything would come to her or things would be administered on a fragmented basis.

Senator Durenberger. But what is behind the notion that there ought to be somebody close to the Secretary and someone close to the HCFA Administrator? Is it to get somebody's attention to the opportunities that lie in this program?

Dr. Rettig. I would predict, Senator, that if there were not, that within a year or two, by virtue of the demands placed on the system from patients and physicians, they would find it prudent to have such an individual.

That is to say, the special character of this program is such that there will be a constant stream of demands, and it simply cannot be ignored and cannot be factored out and distributed to the regular elements in the system.

The question you asked about intermediaries earlier is precisely the point. If people have a high volume of work and many fish to fry, so to speak, how attentive are they going to be to the end stage renal program?

Senator DURENBERGER. Let's talk about networks. What function can a networklike apparatus perform? You have talked about data collection, conflict resolution, and easing market entry. I talked earlier about utilization review, and quality. Is there something basically wrong with trying to have networks out there, or have we made mistakes in setting them up, financing them, and giving them a charge? According to testimony, some networks have been captured by providers. What is the problem and what would you suggest as a resolution?

Dr. RETTIG. For my purposes, the only rationale justifying networks when they were initiated was that of quality of care, a medical review function.

I do not believe that a top down monitoring system to measure quality of care has been established and can be established. And I think that function is unrealistic, cannot be performed. And the basic rationale originally is no longer valid. I have previously written that on that basis, networks should be eliminated.

Now there is a more recent rationale and that is that networks have begun to collect data. They were not designed to collect data. They were designed to receive data and benefit from the data system. But, in fact, they have been employed within the data system. They may be suitable for data collection purposes.

I have also suggested in my testimony that if retained, networks should have patient committees. That is to say they might be a vehicle by which you could create mechanisms that give patients access to this program, give the beneficiaries of this program direct access to their Government.

Beyond those two functions, I do not think that networks are particularly useful. I think they do not ease entry but constitute a barrier to entry.

Senator DURENBERGER. I can see how networks might constrain entry but easing entry could be a positive function for them.

Dr. RETTIG. And I do not believe they resolve conflict, unless there is a predisposition to resolve conflict beforehand. The major cities of this country, with large provider institutions, will always have conflicting relations among them. I think the health planning system and the networks indicate how cumbersome it is to rely on such administrative apparatus.

Senator DURENBERGER. Is there anything we can do, short of substantial change in the reimbursement system, to ease market entry and stimulate competition?

Dr. RETTIG. Well let me say this, that one reason for my critique of networks is that they divert attention from the main character of this program, which is financing health care. I think the reimbursement policy drives the program. I think the fundamental approach to any question of introducing more competition has to be centrally preoccupied with reimbursement policy and not with peripheral organizational questions.

Senator DURENBERGER. Are there areas of the country in which PSRO's might play some role with respect to ease of entry, quality, and utilization?

Dr. RETTIG. The short answer is I don't know. A slightly longer answer is that PSRO's have focused on inpatient care, and the bulk of ESRD treatment is outpatient care.

I also think that the Government might undergo one of those rather cumbersome learning experiences of several years' duration with PSRO's, and the end result might well be where we are today—the discovery that this top-down administrative monitoring system doesn't work well to measure quality on a recurring basis.

Senator DURENBERGER. Senator Baucus?

Senator BAUCUS. Thank you, Mr. Chairman. Doctor, I have several questions. I will try to be as brief as possible to save time here.

In your judgment, should the policy perhaps be coordinated in some unit someplace, not necessarily within HCFA but some unit someplace, so that one, two, or three people are together in the same unit working on policy rather than the alternative apparently preferred by Miss Davis which would be to farm out the various functions within the various departments and bureaus and sections, wherever they are, within the department?

Dr. RETTIG. Well, I think it would be helpful to have somebody, not necessarily full time, but somebody in the Secretary's office who, in addition to various other things, carried the ESRD portfolio; who was knowledgeable about the ESRD program. I think that the absence of such person in the past has resulted in a good deal of churning at the Secretary's level and in a good deal of delay in the formulation of policy in response to congressional legislation.

At the HCFA level, I am not necessarily advocating the present arrangement, but I do think somebody has to be deputized to be principally responsible for coordinating renal functions within HCFA.

Now my preference is that that be the reimbursement policy locale. I stress the importance of the reimbursement policy unit, but one can think of other arrangements.

All administrative solutions, in my judgment, are second best. There is no best solution. So we are dealing with an imperfect world. But I do think it is necessary to have somebody to whom you can direct the question, short of the Administrator, every time something comes up between the distributed parts that they cannot resolve themselves.

Senator BAUCUS. In your judgment, how many patients are presently on institutional dialysis; that is, centers that can be shifted to home dialysis?

Dr. RETTIG. Well, let me answer it this way. The easiest way to put people into the home setting is not to shift from institutional to home dialysis but to shift the proportion of new patients going into the home setting.

I happen to have been witness to this debate about home dialysis for a long period of time. I do not think there is an analytical solution. I do not think the medical community can agree among themselves about a preferred clinical solution. The data reflect fairly major disparities in the distribution of views and of patients across the country.

I draw the conclusion, Senator, that there is a political solution which we might think about; namely, 20 percent; that we set de facto a target at 20 percent of the patients treated at home. It is something like the all European average. It is doable in every network in the country. Some are twice that level now, so we know that we wouldn't be penalizing patients unduly by moving to that level. We are actually approaching that level. Twenty percent would be sort of OK. And I think sort of OK is about where we are going to come out on this business. But that is a decidedly political solution, and it is a message that ought to be conveyed by you and the committee to the Administration because I do not think they have the capacity to arrive at that judgment themselves.

Senator BAUCUS. Assuming we had a 20-percent level, what would the cost data be?

Dr. RETTIG. I am not able to say. Somebody could compute that, but one would have to sort of look at the numbers, number shifted, what the cost movement are.

Senator BAUCUS. I take it from your answer, too, that other countries do not have the same reimbursement procedures that we have in America.

Dr. RETTIG. We know relatively little, in a comparative sense, about what other countries do. We know that in the United Kingdom where the home dialysis proportion is substantially higher than here, that there is very strong reason to believe they are rationing access to care. But then again, in Great Britain, they are devoting less than 6 percent of their gross national product to health care in the first instance. So they are rationing across the board in a variety of ways. So there are a lot of tricky problems in there.

Senator BAUCUS. You mentioned that data collection could be better. What data do you think should be collected? If you were setting up the system, what would you like to have? What kind of data would you like to have?

Dr. RETTIG. Well, survival data would be helpful. And a combined registry that tracks patients, both transplant and dialysis patients, would be useful.

I indicated a strong preference for cost analysis data as one suggestion. I am not expert on data collection, but let me give you a structural response to your question.

I do not think the ESRD program will get a good data system until the Secretary and the Administrator, day in and day out, ask for good data. And that is one of the reasons, Senator Durenberger, for my saying somebody ought to be in charge.

What happens in public agencies is that the data function floats down to the lowest level of the bureaucracy, and they go through an inordinate amount of churning, and they become captive of either the bureaucratic processes or external influences, if there is no strong, constant demand from the top that they generate good quality data.

And so without answering your question, Senator Baucus, I think there is a structural need that does not exist in the system at the moment and that has to be there.

Senator BAUCUS. I think you are raising a point that in fact I think is analogy to it. In almost any organization, whether the quality of the organization is of high quality or not, in a large respect it depends on who is at the top, who is the head of the organization, chances are much better than the rest of the organizations.

Dr. RETTIG. It is not a matter necessarily of competence, it is also a question of the incentives that drive behavior of the executives.

The chief executive officer of a private firm always wants good data. The bottom line is dependent on good quality data. Those same incentives do not drive public officials unless the Congress and the Secretary and the Administrator say—we want it, we need it.

Senator **Baucus**. Thank you very much.

Senator **Durenberger**. Thank you very much, Doctor. We appreciate your being here.

[The prepared statement of Richard A. Rettig follows:]

SUMMARY OF TESTIMONY BY
RICHARD A RETTIG,
SENATE FINANCE COMMITTEE,
SEPTEMBER 28, 1981

1. The ESRD Program has a special character that guarantees a high level of continuous demands on elected and appointed officials.

2. Organizational needs related to the program include:

   - A single designee to carry the ESRD portfolio for the Secretary.
   - A single designee to report on ESRD to the HCFA Administrator and Deputy Administrator.
   - A strong reimbursement policy capability.
   - A strong cost analysis group.
   - A strong medical data group.
   - A strong "exceptions" management capability.

3. Networks absorb substantial HCFA administrative resources that might be used better for other purposes. Their capabilities are sufficiently limited so that they should be eliminated or modified.

4. Facility certification is based on a 1973 policy to limit treatment capacity. Change toward a more competitive policy should be preceded by a comprehensive analysis of the economic, legal, administrative, and medical implications and by the preparation by Committee staff of a specific proposal.

5. Patient representation should be strengthened by patient committees in networks (if the latter are retained) and by direct channels of access to the program.

6. A patient-oriented study of the cost profiles of 3 samples of patients -- those treated primarily in the hospital, limited care, and home outpatient settings -- should be undertaken.

7. The ESRD Program has created a government-made market in which all incentives for cost control derive from federal reimbursement policy.

Senator Dole, Senator Durenberger, Members of the Health Subcommittee:

My name is Richard A. Rettig. I am Professor of Social Science and Chairman of the Department of Social Sciences, Illinois Institute of Technology. Until August of this year, I was a Senior Social Scientist at the Rand Corporation. During my six years at Rand, I conducted research on the End-Stage Renal Disease Program of Medicare, some of it supported by the Health Care Financing Administration. My writings, including a report, Implementing the End-Stage Renal Disease Program of Medicare, have been made available to the committee and its staff. The views I express in my testimony today are personal and do not represent any official position of IIT, Rand, or any agency supporting my research.

Since today's hearing deals with program operations and management, I wish to comment briefly on various organizational issues confronting the ESRD Program. Before doing so, however, it is useful to indicate the special nature of the ESRD Program and the way this special character gives rise to certain organizational and administrative needs.

THE SPECIAL NATURE OF THE ESRD PROGRAM

The ESRD Program differs from the normal Medicare program in a number of ways. The distinctive features include the following:

- The program reimburses life-saving treatment by dialysis and transplantation, treatment that represents the fruits of the large-scale, sustained federal government investment in biomedical research and development made since the end of World War II.

- Patients require treatment on a continuous basis, and this results in very high annual costs per patient and the high costs of the program.
- No immediate prospects exist for any significant new treatment or preventive capability, so the program and its associated cost burden is likely to continue for another decade or more.
- There now exists a growing number of individuals whose lives are being sustained by the ESRD Program. There also exists a relatively small, highly trained cadre of nephrologists and transplant surgeons who are primarily involved in the treatment of patients having end-stage renal disease. So the program beneficiaries and their agents are clearly identified and highly articulate, and predictably will bring their demands to the government.
- The "market" for end-stage renal disease medical services created by Congressional inclusion of Section 2991 in the Social Security Admendments of 1972 is a government-made market, unlike the general Medicare program, so the behavior of patients, physicians, and provider institutions takes place within contraints and incentives established almost entirely by Medicare policy.

These features give the ESRD Program its special character within Medicare. They insure that policy issues related to the program will arise continuously and will command the attention of Members of Congress and high-level officials in the Department of Health and Human Services and the Health Care Financing Administration. Many officials would like to ignore the ESRD Program, or treat it as just another familiar aspect of Medicare. But its special character guarantees that it cannot be treated just like any other aspect of Medicare. Most certainly, one cannot deal with the policy issues raised by the program by ignoring them.

It is also useful to remember that our scientific, technological, and clinical prowess is unlikely to cease pushing forward the frontiers of medical treatment. No reason exists to think that dialysis and transplantation represent the last we shall see of expensive, life-saving treatments. No reason exists to regard these treatments as historically unique phenomena. The reimbursement of heart transplantation is now under active consideration. The prospective use of an artificial heart draws closer. We need to learn form this experience with end-stage renal disease so that the Congress, the executive branch, the medical profession, and the public can better grapple with similar situations that are bound to arise in the future.

CAPABILITIES NEEDED TO ADMINISTER THE ESRD PROGRAM

The special nature of the ESRD Program will generate a continous demand on the attention of elected and administrative officials. This fact-of-life strongly suggests some needed administrative capabilities for both the Department of Health and Human Services and the Health Care Financing Administration.

In the Office of the Secretary:

- The Secretary should designate a single individual to carry the ESRD portfolio on his behalf. This individual might be located either in the Office of the Assistant Secretary of Health or in the Office of the Assistant Secretary for Planning and Evaluation. He or she should follow the program regularly, understand the current issues, be the focal point of relations with HCFA, and pull together the views of the several units in the Office of the Secretary when the occasion requires it. Not since early 1977 has there been such an individual in the Secretary's Office. This lack has resulted in delay and confusion in policy formulation at the Department level.

In the Health Care Financing Administration:

- The Administrator should designate a single individual to report to her and the Deputy Administrator on ESRD matters and to function as a focal point within the agency for internal coordination.
- A strong reimbursement policy organizational capability is needed to deal with the recurring reimbursement policy demands on the program. For all the discussion about ESRD networks, the program is basically a financing one, for which a reimbursement policy capability is absolutely essential.

  Indeed, from the creation of HCFA in early 1977 through 1978, the existing reimbursement policy capability was basically decimated by retirement, reassignment, and the general effects of reorganization. One adverse consequence was that the substantial reimbursement policy demands placed on the agency by the 1978 legislation occurred after this once-strong capability had been vitiated and necessitated its reconstitution.

- A strong cost analysis group is needed. One of the most recurring demands raised by the public, the press, the medical community, policy analysts, and others, is for good data on the costs of the program. It would be extremely useful if HCFA would create an internal group that could conduct a few large cost studies and a continuing stream of small, discrete cost studies. It was recently reported, for example, that of the 43,100 ESRD beneficiaries in the program in 1979, fully 19,500 were also receiving monthly disability benefits from Titles II and XVI. It would be useful to have a cost analysis group able to analyze the question of the disability benefit payments to ESRD beneficiares and publish a report. Especially now when HCFA is considering the possibility of reimbursing heart transplantation and when the successful implantation of an artificial human heart draws closer, this kind of cost analysis capability appears more necessary than ever.
- A strong ESRD medical data acquisition and analysis group is needed. The ESRD Medical Information System suffered in its early years from a variety of problems. It may now have overcome these. But the program has yet to demonstrate an ability to generate a minimal amount of high quality descriptive data in a regular way. The most telling comment about the ESRD Program's 2nd annual report was by the Deputy Editor of the New England Journal of Medicine -- "Twenty-seven pages of

information about transplantation and nothing about survival rates."

The expectation of effective administration and implementation of government programs is predicated on the assumption that departments and agencies will learn from experience. The inability to generate data and analysis pertinent to program administration, however, vitiates the possibility of learning by experience. Under such circumstances, the Congress and everyone else is left trying to formulate policy in the dark. Three years have now elaspsed since the 1978 legislation and incentive reimbursement regulations for dialysis facilities have yet to be issued as a final rule. Although there are some very hard policy choices to be made relative to these regulations, this inordinate delay is partly due to the absence of data on which to make prudent and defensible policy determinations. Both cost analysis and medical information data capabilities are needed. Until the Congress, the Secretary, and the Administrator insist that such capabilities be established, useful, good quality data will not be forthcoming.

- A strong operations capability is needed, especially for reviewing exceptions requests. Had a more rigorous review been made, for example, of the reimbursement exception requests, it is unlikely that HCFA would have drifted so far toward the two-tiered reimbursement rate structure that now exists for outpatient dialysis.

ESRD NETWORKS

This brings me to networks, on which I will comment briefly.

- Networks have absorbed a large portion of HCFA administrative resources that might have been put to more useful work. The program, after all, is not about how to administer a cumbersome, decentralized, quasi-government, quasi-private administrative apparatus, but primarily about financing care.
- Networks themselves have extremely limited capabilities:
  - They contribute nothing to increased patient access to treatment.
  - They contribute nothing to cost control.
  - They basically represent provider interests and only minimally represent patient interests.
  - They cannot resolve conflict among physicians and provider institutions unless a disposition to resolve conflict exists independently.
  - They are used on occasion to limit the entry of new treatment facilities, primarily for reasons of financial self-interest of previously certified facilities.

  - Most seriously, they cannot demonstrate a measurable beneficial effect on patient well-being due to inadequate data, inadequate measures of quality, the infrequency of measurement, the reliance on records rather than direct observation, and the concurrent operation of more significant factors that influence quality of care.

o Given these limitations, networks ought to be eliminated or modified to perform functions they can achieve. In particular, they now collect data, a purpose for which they were not originally intended but for which they might be well suited.

SHOULD ESRD FACILITIES BE CERTIFIED?

The Committee has asked about the function of networks in the facility certification process, about the certificate-of need requirements of the health planning system, and the annual facility survey and recertification. These are all fairly recent manifestations of a policy adopted in 1973.

The policy adopted in June 1973 imposed a freeze on the establishment of new facilities and the expansion of existing facilities. This freeze was predicated on a desire to avoid an oversupply of dialysis beds, a prospect which was viewed as analogous to the general problem then facing Medicare of an oversupply of hospital beds. It was believed that restricting the growth of treatment capacity to some reasonable relationship to the growth in the patient population would dampen the pressures for cost inflation that had resulted from the hospital over-bedding situation.

The feature that was different in the ESRD case, however, was that reimbursement was based on a screen or ceiling that applied equally to all outpatient dialysis treatment at that time. The screen provided a powerful financial incentive to providers and facilities to fully utilize existing capacity and penalized oversupply by reimbursing on a per treatment basis. So the freeze, in one sense, was superfluous to cost control.

The policy of the freeze, followed by one of controlled growth in treatment capacity, preceded the imposition of certificate-of-need through the health planning process, as well as the facility certification role of the networks, and the annual survey and recertification process. We ought to be clear, therefore, that we are dealing with the original policy, not just with its more recent manifestations.

It is now proposed by some that the system be deregulated and the relations among providers and facilities be made more competitive. That may be an appropriate policy to pursue. But some caveats need to be raised at this juncture relative to such a proposed course of action:

- A comprehensive analysis of what such policy might entail has not yet been performed. Such a study would necessarily include not just static economic analyses, but would also have to consider legal and institutional aspects of change in a dynamic context.
- Assuming an ideal competitive system can be stipulated, attention would be required regarding the "transaction costs" of getting from here to there.

- In process terms, it would be useful to have a specific proposal, perhaps prepared by the Committee staff, which could be subjected to the scrutiny of further hearings. Expressions of dissatisfaction with the present system may be the basis for rethinking existing policy, institutions, and process. Such expressions, however, are no substitute for a specific, fully developed proposal.
- In a word, we have yet to have an Alain Enthoven write an adaptation of Health plan for the ESRD Program.

STRENGTHEN REPRESENTATION OF PATIENT INTERESTS

The ESRD patient who is treated on a recurring basis becomes well informed about the nature of his or her disease and its treatment. This contrasts with the general patient who experiences new and unusual symptoms for an acute illness episode. The potential exists, therefore, to take advantage of an informed patient population.

If networks are retained, each network should be required to have a patient committee, not just a patient advisory committee or patient representation on the physician-dominated Network Coordinating Council and Medical Review Board.

To establish incentives for maintaining high quality of care, patients should have access to direct and dedicated channels of communication with the program. These channels might be used by patients for the reporting of accidents, near-accidents, and persistently unsatisfactory conditions of care. The mere existence of such channels for use by patients should provide a structural incentive to physicians to be vigilant about maintaining high quality care. I believe that such channels constitute a more effective guarantee of quality of care than any top-down, data-dependent monitoring system that can be devised.

A PROPOSED COST STUDY

Much attention has focused on the cost of "producing" dialysis in the hospital, limited care, and home settings. The discussion has made clear the difficulty of establishing the basic facts of the matter.

The discussion is conceptually flawed by its focus on the treatment unit, not the patient, and by the tendency to overly restrict the cost analysis to Part B expenditures.

The program has existed for more than eight years and there are now over 50,000 enrolled beneficiaries. It should be possible to draw three representative samples of dialysis _patients_ who are treated primarily (more than 6 months out of every year) in the hospital, limited care, or home outpatient settings. Cost profiles can then be developed for each of these three samples, which can be stratified by age, sex, race, the presence or absence of diabetes, and length of treatment. The cost profiles I have in mind would include the range and average annual costs for each of these three samples for the following categories:

- Part A expenditures
- Part B expenditures
- Patient copayment expenditures (by Medicaid, coinsurance, or self)
- Monthly disability expenditures (from Titles II and XVI)

Such a study would not be easy to do if the past is any guide. But it would offer a more discriminating picture of the full costs to Medicare and the Social Security disability program of treating patients in these three different settings, and move away from the narrow issue of the relative efficiency of treatment providers reimbursed under Part B.

ESRD:GOVERNMENT-MADE MARKET

I realize that you plan a subsequent hearing on reimbursement policy issues. Let me close, then, with this final thought. There is no natural market for the provision of treatment for end-stage renal disease. Without government intervention, only the very wealthy would be able to finance care. Without Medicare, we would revert to the situation that existed before 1973: some Public Health Service grant and contract money might be available; some state government funds might be provided; some private insurance might cover kidney failure; some community fund drives might be launched to keep John Doe alive another year. But people whose lives are now being extended would die sooner, many without any treatment. It is that simple.

Reimbursement policy for end-stage renal disease, it must be remembered, is formulated in a government-made market. The behavior of physicians, patients, and providers relative to dialysis (whether in the hospital, limited care, or home setting) or transplantation is shaped by the constraints and incentives that flow directly from federal government policy.

The current system is second best. But there may be no "best" system. There is a cost side as well as a benefit side to almost all policy initiatives, as is true for government organization and reorganization. Prudence should characterize policy changes. The precise nature and scope of "competition" should be analyzed carefully, its presumed benefits and its potential costs weighed thoughtfully.

I hope these remarks are useful to the Committee's deliberations. If I can be of further help to the Committe or its staff, I will be happy to cooperate.

Senator **Durenberger**. Our next witness is Margaret Diener, executive director, National Association of Patients on Hemodialysis & Transplantation, Inc., New York, N.Y. Margaret, welcome.

STATEMENT OF MARGARET DIENER, M.P.H., EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF PATIENTS ON HEMODIALYSIS & TRANSPLANTATION, INC., NEW YORK, N.Y.

Ms. **Diener**. Thank you very much.

I want to thank you for the opportunity to appear here today on behalf of the association which is more commonly known as NAPHT.

I am Margaret Diener, executive director of the association, and I am appearing today to summarize the written testimony already submitted by our president, John Newmann, which we would like to have entered in the record.

[The prepared statement of John Newmann follows:]

STATEMENT OF JOHN NEWMANN, PH. D., M.P.H., PRESIDENT, NATIONAL ASSOCIATION OF PATIENTS ON HEMODIALYSIS & TRANSPLANTATION, INC.

Mr. Chairman and Members of the Committee, I wish to thank you for the opportunity to appear here today on behalf of the National Association of Patients on Hemodialysis and Transplantation, more frequently known as NAPHT. I serve as President of this Association, and I am a dialysis consumer of ten years.

NAPHT's membership includes approximately 10,000 kidney patients from every state as well as from Guam, Puerto Rico, and the Virgin Islands. Kidney patients generally, and NAPHT members in particular, have developed a great deal of knowledge and experience both about renal failure and about the ESRD program. My comments today are based on information received from individual patients around the country as well as from the leadership of our 30 local chapters.

My comments today will address the specific questions about utilization and access, program management, quality of care, and data and research that this Committee is reviewing as well as addressing several other areas of concern to us. The continuation and success of this program are of critical concern to us. Without the program, many of us would not be alive today.

Before addressing the specific topics, I would like to remind this Committee that the ESRD Program has been, by many standards, an extraordinarily successful one. The federal funding provided has not only been responsible for keeping literally tens of thousands of people alive, but also in enabling them to continue to be productive members of our society. On the NAPHT Board of Directors, for example, we have tax-paying patients who are engaged in law practice, civil service, accounting, secretarial service, banking, medicine, and education. The success of the ESRD Program has occurred with a high degree of cost containment, which should be a source of pride to those who designed and administer the program. As serious analysts of this program have pointed out, the vast majority of increased expenditures over time has been due to the increasing numbers of patients, whereas real costs per patient have stabilized or decreased.[1]

NAPHT is very appreciative of the wisdom and good judgment shown by this Committee and by Congress during the recent budget process. In the general rush to reduce federal expenditures, we commend this Committee for not losing sight of the human needs of our members and acting to insure the continued availability of treatment to all who need it while finding creative ways to restrain the continued growth of costs of the program. On behalf of our members and all those with kidney failure, we express our sincere gratitude to each of you for preserving this life-saving program.

We understand that this Committee will be holding hearings at a later date to review reimbursement issues of the program. We would like, however, to take just a few minutes today to comment on the recently passed federal budget. We urge this Committee to utilize its oversight capacity to insure that the Administration act promptly and carefully to implement that legislation. More specifically:

1. We strongly recommend that regulations be developed and distributed widely with the greatest possible speed. Uncertainty as to the nature of future reimbursement policies has a chilling effect on both patients and administrators. Failure to expand existing facilities or develop new ones

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[1] Rettig, Richard A. and Ellen L. Marks, "Implementing the End-Stage Renal Disease Program of Medicare," Rand Corporation, Santa Monica California, 1979.

to meet increased demand can result from lengthy delays in implementation of the new reimbursement rates.

2. We urge that the rates be reasonably constructed and consider the full range of services needed for optimal patient care and efficient operation of facilities. Adequate patient care staff for the mix of patients in a facility, nutritional and psychological support services, and social services are needed for patients to achieve their full rehabilitation potential. Rates should be based on audited costs of units which not only provide these services but have patient populations which exhibit acceptable levels of rehabilitation and return to employment. Rates based upon facilities which provide the least expensive treatments but do not have acceptable levels of rehabilitated and working patients should not be established. Therefore such rate setting should include cost information also based upon patient data according to age, diagnosis (with or without complicating diseases such as diabetes mellitus and/or cardiovascular disease), rehabilitation and employment status.

3. We urge continued careful monitoring of costs and adjustment of reimbursement rates to compensate for increased or decreased costs and inflation.

4. We support and applaud the action of this Committee in recognizing the need for a dual rate structure for free-standing and hospital-based facilities. We would view with grave concern any reimbursement mechanism which would make it economically impossible for hospital-based facilities to continue to provide renal care.

5. We continue to support the composite rate as a viable method of controlling costs while providing incentives for increased use of home dialysis - a modality of treatment which has been underutilized in our view.

We will address home dialysis in more detail in a few moments.

We would now like to turn our attention to the specific areas that this hearing is considering.

A. Utilization and Access - Access to treatment is the most basic concern of our Association. The renal program has made some form of treatment accessible to virtually all who need it, but it has not succeeded in making all forms of treatment available to all patients. We do not endorse or advocate any one modality or location for treatment. Indeed, we recognize that different modalities are best suited for different people. Unfortunately, many patients do not have a choice of therapy but are almost routinely placed on in-center hemodialysis.

As already mentioned, home hemodialysis appears to be an underutilized mode of treatment. We frequently receive inquiries from patients who state that they would prefer to be on home dialysis but are unable to do so because of lack of training facilities in their area, discouragement from their physicians, increased out-of-pocket costs, and/or lack of back-up support including respite paid aides.

Patients also find that they do not often have a choice of facility and/or physician. The certificate-of-need process has succeeded in curtailing the number of facilities, and therefore patients are usually unable to transfer to another center if they are not satisfied with the treatment they are receiving. If there is another more convenient center nearby, patients can seldom transfer to it for at least two reasons:

1. Since their lives literally depend upon their current physician's service, they are reluctant and often fearful of suggesting termination of service and requesting a transfer.

2. For those who have the courage to switch physicians, they often find there is simply no room in the other facilities. This seems particularly true in large urban areas. In more rural areas, there is usually only one dialysis facility available.

Another access problem for patients is choice of staff. As we indicated in our public comment when the Department of Health and Human Services published the Proposed Rule requiring open staffing of dialysis units, we wholeheartedly endorse that practice. Criteria related to the provision of quality care to patients should be the only criteria for staff qualification in a facility.

There is one other access problem we would like to mention and that is access to evening hour treatment. While we recognize that it may not be feasible or economically sound for every facility to offer evening dialysis, we strongly endorse the idea of requiring some evening shifts in a given geographical area. It is clearly impossible for a patient to work during a normal 9 a.m. to 5 p.m. day if he or she must undergo dialysis during those hours.

B. Program Management - One of the questions this Committee is considering is the use of a single intermediary for processing of Medicare claims for the ESRD program. From our viewpoint, the use of a single or a very few intermediaries would be preferable to the current situation. Patients are concerned about costs, and it would be easier to deal with a few intermediaries than with the current number in addressing cost concerns and other questions.

We now turn to the ESRD Networks. Although we have sometimes been concerned about the apparent unresponsiveness of Networks to patient concerns in the past, we have seen substantial improvement in this area. We therefore recommend that they be continued although with some new direction and increased emphasis on patient concerns. Many patients are very sophisticated about their treatments, both medically and administratively. The Network system has provided a point of contact at a reasonably local level through which patients can address medical and administrative problems and complaints. For example, in Network 25 in Downstate New York, several patients pointed out the need for geographically accessible facilities, particularly at the eastern end of Long Island, when recommendations for approval of new facilities were being considered.

Assuming the continued funding of Networks, we would urge the following:

1. Increased participation in the Network activities through patient advisory committees and encouragement of greater participation in the Coordinating Councils and Executive Committees. Our Association stands ready to help patients more effectively participate.

2. Mandated patient participation in the Medical Review Boards. We believe that this would strengthen this very important function and impact favorably on the quality of medical care provided.

3. Improved patient grievance procedures both within facilities and through the Network with unresolved problems of a medical nature being referred to the Medical Review Boards for action.

4. Greater authority of the Networks to recommend withholding of reimbursement from facilities which are found to provide inadequate quality of care.

5. Continued and expanded collection of patient data.

6. Greater involvement and resolution of problems on a regional basis such as assuring access to all modalities of treatment for all patients,

insuring the availability of evening treatments in any one geographical area, and coordinating rehabilitation services in a given region.

If Congress or the Administration decides to defund the Networks, we are greatly concerned that an important local interface between the medical care system and the patient population will be lost. In that event, we would most urgently recommend that a patient advocate system be established within the regional offices of the Department of Health and Human Services to deal exclusively with the renal community. Ideally this ombudsman would be a patient who could assist and advise other patients. Such a person would need adequate authority and support from the medical community and the federal bureaucracy in order to be effective. Our Association would be most delighted to offer further advice and its experience in dealing with patient grievances and complaints should such a system be implemented. However, we would reiterate our earlier point recommending improvements in the current system rather than the elimination of that system and the development of a new one.

C. Quality of Care - Access to care as our primary concern is dependent upon our equally important concern with the quality of that care. While survival is the initial concern of new patients, the quality of life becomes the paramount concern once survival is assured. Quality of life is simply not possible when the quality of the medical care rendered is less than optimal.

We would be the first to recognize that there are a number of factors including complicating medical conditions and age that have an impact on the quality of life and the physical appearance and condition of an individual. However, we are deeply concerned that quality of care is almost always measured by mortality, not morbidity. Licensure and certification reviews too often look at process measures rather than outcome measures. Rates of hospitalization, average duration of fistula before revision is necessary, frequency of blood transfusion, frequency of dialysis and post dialytic complaints, and measures of physical well-being are a few of the parameters which could measure, on a comparative basis, the quality of care rendered by transplantation and dialysis facilities. For example, a facility which has a very high frequency of fistula revisions may need to retrain its staff on venipuncture technique - or teach its patients to insert their own needles.

There are other groups more qualified than we to develop this type of quantitative measure of the quality of care, and we strongly urge them to do so. Some Networks are developing this information. The American Association of Nephrology Nurses and Technicians is developing outcome criteria for nursing care. We believe that this data could best be correlated by the convening by the National Institutes of Health or the National Center for Health Care Technology of a consensus conference on outcome morbidity measures of the quality of dialysis and transplantation care, and we urge consideration of such a conference.

There is discussion within the renal community of replacement of the current Medicare certification process by a certification by the Joint Commission on the Accreditation of Hospitals. The concept has merit, and we favor such an approach if it supported and perhaps improved upon existing standards of care.

D. Data and Research - Along with so many others in this field, NAPHT has been concerned about the lack of reliable data about the renal population, its treatment, and the outcome of this treatment. We commend the Health Care Financing Administration and the Networks for the greatly improved data provided for 1980. However, more data is needed. As noted, we would like to see more data on morbidity of patients. We would also like to see data on the physical and occupational rehabilitation of patients. Morbidity, rehabilitation and employment data are critical to an analysis of how well the program is accomplishing its objectives, which facilities are useful examples of high quality care and which require improvement, and what patient age groups and diagnosis groups require varied treatment and should have individually tailored rehabiliation programs.

Data are needed (perhaps through demonstration projects) to focus on the impact of the program administration on both the cost and quality of care rendered by the program. For example, rehabilitation and return to employment can be cost effective for the federal government through reduction in disability payments and increases in income tax payments of employed patients. To what extent are rehabilitation and employment programs cost effective, i.e. vocational rehabilitation counselors specifically assigned to one or more dialysis/transplant centers, exercise programs and stress reduction programs offered by a facility to its patients, evening dialysis as an incentive to return to work (we know its absence is clearly a disincentive), etc?

We recognize that this hearing is concerned with the administration of the ESRD program and not the Disability Insurance Program. However, we would like to point out to the Committee that Work Incentive Experiments are about to begin for the disability program to determine ways in which benefits can be restructured to maximize a return to employment. Many dialysis and transplant patients do receive disability benefits. Although they share many of the same incentives and disincentives as others who are disabled, we believe that there are some unique characteristics of this population, most notably the fact that their Medicare coverage is not dependent on their disability status. We have therefore urged the Social Security Administration to track this population as a subset within the framework of the Work Incentive Experiments and urge this Committee to support that recommendation.

One of the questions we are most frequently asked is how a patient can choose a "good" facility in which to seek care. We are not able to answer that question at the present time. Indeed in seeking comparative mortality or morbidity data collected by Networks, we have been refused on the basis that such information is confidential. While we fully support the confidentiality of individual patient medical data, we believe that the patient community must have access to facility-specific data. Patient freedom of choice and informed consent are meaningless if patients are denied the information on which to give consent and make choices.

We thank you for the opportunity to appear here today and express our opinions and concerns on these important topics. Our overriding concern remains that high quality care be available to all who need it. We offer our ongoing assistance to assure that this care is available. We would be happy to answer any questions this Committee might have.

Ms. DIENER. NAPHT's membership currently includes approximately 10,000 kidney patients from every State as well as from Guam, Puerto Rico, and the Virgin Islands. My comments today are based on information received from individual patients as well as from the leadership of our 30 local chapters.

Before addressing the specific topics this committee is reviewing, I would like to remind you that the ESRD program has been, by many standards, an extraordinarily successful one.

The Federal funding provided has not only been responsible for keeping literally tens of thousands of people alive, but also in enabling them to continue to be productive members of our society.

As an organization, we are very appreciative of the wisdom and good judgment shown by this committee and Congress during the recent budget process.

In the general rush to reduce Federal expenditures, we commend the committee for not losing sight of the human needs of our members, and acting to insure the continued availability of treatment for all who need it, while finding creative ways to restrain the continued growth of the cost of the program.

On behalf of all of those with kidney failure, we express our sincere gratitude to each of you for preserving this lifesaving program.

We understand that the committee will be holding hearings at a later date to review the reimbursement issues of the program, but I would like today to urge the committee to utilize its oversight capacity to insure that the Administration acts promptly and carefully to implement that legislation. There are some specific suggestions in our written statement.

Turning now to the specific areas that the hearing is considering, first, in terms of utilization and access. Access to treatment is the most basic concern of our association. The renal program has made some form of treatment accessible to virtually all who need it, but it has not succeeded in making all forms of treatment available to all patients.

Home hemodialysis particularly appears to be an underutilized mode of treatment. We frequently receive inquiries from patients who state that they would prefer to be on home dialysis but are unable to do so because of the lack of training facilities in their area, discouragement from their physicians, increased out-of-pocket costs, and/or lack of backup support, including respite paid aides.

Ms. DIENER. Patients also find that they often do not have a choice of facility or physician. The certificate-of-need process has succeeded in curtailing the number of facilities, and therefore patients are often unable to transfer to another center.

Another access problem for patients is choice of staff. We wholeheartedly endorse requiring open staffing of dialysis units. Criteria related to the provision of quality care to patients should be the only criteria for staff qualification.

In terms of program management, I want to focus on one aspect of the ESRD network system. In the past, we have been concerned that networks have not been particularly responsive to patient concerns. We have recently seen some improvement. We therefore would prefer that networks continue, but with new direction and increased emphasis on patient concerns. And, again, we have a number of specific suggestions.

If, however, network funding is discontinued, we are concerned that an important local interface between the medical care system and the patient population would be lost. We would urge Congress to insure that some mechanism would remain for patients to address both medical and administrative complaints.

We believe that some kind of patient advocate system within the regional offices of the Department of Health and Human Services might do it.

In terms of the quality-of-care issues, we have been very concerned about quality of care in addition to access to care. While survival is the initial concern of new patients, the quality of life becomes paramount once survival is assured. Quality of life is simply not possible when the quality of medical care rendered is less than optimal.

We would be the first to recognize that there are many factors that impact on quality of life and quality of medical care; however, we are deeply concerned that the current quality-of-care measures, which are minimal, utilize mostly mortality data or process criteria. Frequency of hospitalization, frequency of fistula revision, blood transfusions, dialysis, and postdialysis complaints are a few of the parameters which we believe could measure, on a comparative basis, the quality of care rendered by transplantation and dialysis facilities.

There are many other groups that are more qualified than we to develop this kind of standard, and we would urge them to do so.

We would recommend that the National Institutes of Health or the National Center for Health Care Technology convene a consensus conference to develop outcome morbidity data to measure the quality of dialysis and transplantation care.

In terms of data and research, we share the concern addressed by many others about the lack of reliable data. We are specifically interested in datum on morbidity, as I stated, as well as on physical and occupational rehabilitation.

One of the questions we are frequently asked is how can a patient choose a good facility and we are not able to answer that. In fact, in seeking comparative data from networks, we have been refused on the basis that this information is confidential. We would not only like to see the data developed, but we believe that patients must have access to facility-specific data. Patient freedom of choice and informed consent are meaningless if patients are denied the information on which to give consent or make choices.

I thank you for the opportunity to be here. And we would be happy to answer any questions.

Senator DURENBERGER. Thank you very much for being here.

Of course, the full statement will be made part of the record.

Your comments on the need for a complaint process imply that patients are often reluctant to complain to the professional that is providing them the service? Would you just tell me briefly how serious and extensive this problem is? Does it vary from one part of the country to the other? And what are the variables where the problem is less severe?

Ms. DIENER. First of all, I think there is some reluctance on the part of patients to complain, but those who do often find that there is no redress of their complaints. So the problem is not just complaints.

As long as a patient has no choice of facility or no choice of physician, they are obviously at a disadvantage and much more reluctant to complain. However, as I said, the problem seems to us often to be that even when they do address a specific complaint, no one does anything about it. There is simply nothing that can be done.

For instance, this morning coming down here from New York, I was responding to a letter from a patient who is being transferred to another facility because the facility at which she is treated is no longer going to treat patients in the evening. She works during the day; she is a schoolteacher. She wants to keep on working. The distance she has to drive to another facility is substantial, and she said I think I am going to have to quit working. What can I do? That is the kind of thing that needs to be addressed, and there needs to be some kind of ability of the system to deal.

Senator DURENBERGER. I asked our last witness about the ease of entry into the system for providers. Is the choice of treatment strictly an issue of information, or are there an inadequate number of alternative facilities?

Ms. **DIENER**. There are facilities to treat everybody, but there is not necessarily the choice of treatment. For instance, in one city I visited a number of patients said they wanted to go on home dialysis. I talked to the director of the facility who said, "I don't believe that patients can treat themselves; therefore, I do not train them."

Their only choice was pulling up stakes for 6 weeks and going to another location for training, and that was for them an insurmountable problem. So there is not every choice or every modality available in every location.

Senator **DURENBERGER**. Can you identify the areas of the country or the networks in which home dialysis is either encouraged or discouraged?

Several people have referred to one of the west coast networks—and I understand we may hear a little bit about it later in the day—that has 40 to 45 percent home dialysis. Are there other success stories and how do they differ from everyone else?

Ms. **DIENER**. I don't really have network or geographic specific data.

Senator **DURENBERGER**. All right.

Can you please characterize the concerns that patients most often bring to the attention of your organization?

Ms. **DIENER**. I would say they cover quite a range of things. It would not be one kind of thing. In terms though of modality of treatment, which has been addressed here, as I said, we view home hemodialysis as an underutilized mode of treatment. And that is based not on any philosophic preference but on the fact that we get many questions from patients about how can I go home, or I hear home dialysis is great but I can't do it. We do not get the opposite kind of thing, a patient saying, "I'm being forced to go home, and I don't want to." So that would be one concern.

Senator **DURENBERGER**. Thank you very much for your testimony. We will recess briefly until Senator Baucus gets back.

[Whereupon, at 3:25 p.m., the hearing was recessed.]

AFTER RECESS

Senator **BAUCUS**. The hearing will come to order.

The next witness will be a panel consisting of Ernest Bauer, of Vienna, Va.; William Blackton, of Reston, Va.; Benjamin Schoen, of Washington, D.C.

We welcome each of you to the committee, and I ask that you proceed in any order that you wish.

STATEMENT OF ERNEST T. BAUER, VIENNA, VA., ACCOMPANIED BY JEAN LEAHY-RAVER, BARBARA LINDSAY, AND DAN JONES

Mr. **BAUER**. Mr. Chairman, my name is Ernest T. Bauer and I am a kidney transplant patient. I received a kidney transplant, a living related donor kidney, from my sister about 4 years ago. Prior to that time I was a home hemodialysis patient for 5 years.

With me today are three fellow patients or people who are related to patients. To my left is Mrs. Jean Leahy-Raver, who is the mother of two sons, both of whom have spent extensive time on dialysis, both hemodialysis and continuous ambulatory peritoneal dialysis, and who now have been successfully transplanted.

Ms. Barbara Lindsay and Mr. Dan Jones, both of whom are transplant patients, having spent many years on dialysis. Mr. Jones, as a matter of fact, is a multiple transplant patient.

I and those I have just introduced are also members of the Patient Advisory Committee of the ESRD Network 23, which is the network operating here in the National Capital area, and which has jurisdiction over the District of Columbia, northern Virginia and Montgomery County, and southern Maryland.

I am currently the chairperson of that Patient Advisory Committee which has a very active program which I would like to share with the subcommittee today.

I understand that Network 23 is one of the few networks in the country that has seen fit to create a patient advisory committee.

Let me just briefly summarize two of the projects and then treat in detail some of the other projects of the Patient Advisory Committee.

We created a couple of years ago what we call a telephone hotline, which is essentially a telephone instrument enabling patients encountering end stage renal disease for the first time to communicate with other patients. We do not dispense medical information or make recommendation on doctor's care or dietary restrictions or anything of that sort. It is strictly a mechanism for communication.

A second element of the patient program that I would like to briefly mention is that we published about a year ago "A Patient Information Booklet on Kidney Disease," and this is essentially the collection and publication of all sorts of information about end stage renal disease services available in Network 23.

This project was researched, written and published exclusively by patients.

About a year ago, the Patient Advisory Committee took it upon itself to communicate with another committee of the network, the medical review board, about patient concerns regarding the quality of kidney care services in the network area. The patient population was concerned that it did not have enough knowledge of renal disease or treatment options and the various modalities for treating end stage renal disease.

I am pleased to tell you that the medical review board of Network 23 subsequently conducted a survey of the patient population and confirmed that many of the concerns expressed in these original communications from the Patient Advisory Committee were in fact true.

At the current moment, the medical review board of Network 23 has a most active program in ascertaining that standards for the delivery of medical services in the area are adhered to, both dialysis and transplant, and that patients are in fact properly informed so as to better participate in the formulation of their own long-term medical plan. I am pleased to say that this program was precipitated by the questioning attitude of the Patient Advisory Committee.

The final element of the current program of the Patient Advisory Committee of Network 23 concerns a legislative initiative which I am particularly pleased to bring before this subcommittee today because it is something that we have recently communicated to both Houses of the Congress.

As you are aware, medicare now covers 80 percent of the medical costs for end stage renal disease patients up until 36 months after kidney transplant. This includes hemodialysis, continuous ambulatory peritoneal dialysis, and surgery for kidney transplantation, as well as the routine medical maintenance and hospital visits that are required subsequent to the kidney transplant.

We and the Patient Advisory Committee of Network 23 submit that this 36-month cutoff provision contained in the law is inequitable and constitutes potentially a financial disincentive for many people to receive a kidney transplant. We accordingly recommend that medicare coverage be extended from the current 36-month statutory limit to the life of the kidney.

Besides, medicare already has too substantial an investment in patients by the time they are transplanted to cease support so arbitrarily at 36 months.

The rationale for this legislative change, together with some statistics on kidney transplantation, and also some estimated costs of this program extension, are contained in an issue paper which is attached to my testimony and which I would like to be made part of the record of this hearing.

While extending the Medicare insurance coverage beyond the 36-month barrier will cost the Government some additional funds initially, in the long run we feel that savings can be realized because patients will be more inclined to seek transplantation as a modality. With the current 36-month barrier in place, however, we suggest that this might be a financial disincentive.

This Patient Advisory Committee program has been advanced by patients and supported by the Network. Had the Network not been in existence, there would in fact be no forum in which to raise such patient concerns and issues.

This, Mr. Chairman, concludes my prepared statement. I and those who I introduced would be pleased to answer any questions on end stage renal disease and networks that you might want to place before us. Thank you very much.

Senator BAUCUS. Thank you very much.

[The prepared statement of Ernest T. Bauer follows:]

STATEMENT OF
ERNEST T. BAUER
SEPTEMBER 28, 1981
SENATE COMMITTEE ON FINANCE, SUB-COMMITTEE ON HEALTH

MR. CHAIRMAN AND MEMBERS OF THE SUB-COMMITTEE:

MY NAME IS ERNEST T. BAUER AND I AM A KIDNEY TRANSPLANT PATIENT. I RECEIVED A KIDNEY TRANSPLANT, A LIVING RELATED DONOR KIDNEY FROM MY SISTER, ABOUT 46 MONTHS AGO. PRIOR TO THAT TIME, I WAS A HOME HEMODIALYSIS PATIENT FOR FIVE YEARS. WITH ME TODAY IS MRS. JEAN LEAHY-RAVER, WHO IS THE MOTHER OF TWO SONS, BOTH OF WHOM HAVE SPENT EXTENSIVE TIME ON DIALYSIS, BOTH HEMODIALYSIS AND CONTINUOUS AMBULATORY PERITONEAL DIALYSIS AND WHO NOW HAVE BEEN SUCCESSFULLY TRANSPLANTED, MS. BARBARA LINDSAY AND MR. DAN JONES BOTH OF WHOM ARE TRANSPLANT PATIENTS HAVING SPENT MANY YEARS ON DIALYSIS. MR. JONES, AS A MATTER OF FACT, IS A MULTIPLE TRANSPLANT PATIENT.

I AND THE MEMBERS OF THIS PATIENT PANEL ARE ALSO MEMBERS OF THE PATIENT ADVISORY COMMITTEE OF END STAGE RENAL DISEASE NETWORK #23, WHICH IS THE ESRD NETWORK OPERATING HERE IN THE NATIONAL CAPITAL AREA AND WHICH HAS JURISDICTION OVER THE DISTRICT OF COLUMBIA, NORTHERN VIRGINIA, MONTGOMERY COUNTY, AND SOUTHERN MARYLAND. I AM CURRENTLY THE CHAIRPERSON OF THAT PATIENT ADVISORY COMMITTEE WHICH HAS A VERY ACTIVE PROGRAM WHICH I WOULD LIKE TO SHARE WITH THE MEMBERS OF THIS SUB-COMMITTEE TODAY.

I MIGHT SAY PARENTHETICALLY THAT ESRD NETWORK #23 IS ONE OF THE FEW NETWORKS IN THE ENTIRE COUNTRY THAT HAS SEEN FIT TO CREATE A PATIENT ADVISORY COMMITTEE AND I AM POSITIVE THAT NETWORK #23 HAS BY FAR THE MOST ACTIVE PATIENT ADVISORY COMMITTEE.

THE PATIENT ADVISORY COMMITTEE OF ESRD NETWORK #23 CAME INTO EXISTENCE ABOUT 3 YEARS AGO WHEN THE NETWORK ITSELF FIRST STARTED.

ONE PROJECT WHICH THE PATIENT ADVISORY COMMITTEE OF ESRD NETWORK #23 HAS SUCCESSFULLY CARRIED OUT IS THE ESTABLISHMENT OF WHAT WE CALL A TELEPHONE HOTLINE. THIS IS ESSENTIALLY A TELEPHONE SERVICE THAT IS HOUSED PHYSICALLY IN THE OFFICE OF THE NETWORK. THE TELEPHONE NUMBER IS ADVERTISED AMONG PATIENTS AND THE PURPOSE OF THE TELEPHONE LINE IS TO PUT PATIENTS IN TOUCH WITH OTHER PATIENTS. WE ARE CAREFUL NOT TO GET INVOLVED IN DISPENSING MEDICAL ADVICE OR ADVICE ON PATIENTS CONDITIONS, ADVICE ON DIETARY RESTRICTIONS; THE TELEPHONE HOTLINE IS MERELY A MECHANISM TO ENABLE PEOPLE WHO ARE ENCOUNTERING THE VERY GREAT DIFFICULTIES OF END STAGE RENAL DISEASE TO DISCUSS MUTUAL CONCERNS AND PROBLEMS AND DIFFICULTIES WITH OTHER PATIENTS WHO HAVE BEEN THROUGH THE SAME EXPERIENCES.

IN ACTUAL PRACTICE, WHAT HAPPENS IS THAT WHEN A PATIENT OR POTENTIAL PATIENT CALLS THE KIDNEY TELEPHONE HOTLINE, THE STAFF OF THE NETWORK DISCUSSES WITH HIM THE NATURE OF HIS CONCERN OF INQUIRY AND THEN REFERS THAT CALL TO WHATEVER VOLUNTEER MEMBER OF THE PATIENT ADVISORY COMMITTEE THEY FEEL CAN BEST RESPOND TO THE CONCERNS AND ANXIETIES OF THAT PARTICULAR PATIENT INQUIRER.

THIS KIDNEY TELEPHONE HOTLINE HAS PROVEN TO BE A WORTHWHILE SERVICE AND WE HAVE PATIENT TESTIMONY THAT IT HAS BEEN HELPFUL.

A SECOND MAJOR ELEMENT OF THE PROGRAM OF THE PATIENT ADVISORY COMMITTEE OF ESRD NETWORK #23 THAT I WOULD LIKE TO CALL TO THE ATTENTION OF THIS SUB-COMMITTEE IS PUBLICATION IN JUNE, 1980, OF A PATIENT INFORMATION BOOKLET ON KIDNEY DISEASE. THIS IS ESSENTIALLY THE COLLECTION AND PUBLICATION OF ALL THE KINDS OF INFORMATION ABOUT END STAGE RENAL DISEASE SERVICES THAT ARE AVAILABLE IN NETWORK #23.

LISTS OF ALL OF THE KIDNEY DIALYSIS CENTERS, HOSPITALS WITH TRANSPLANTATION SERVICES, TELEPHONE NUMBERS, DOCTORS NAMES AND NURSES NAMES. IT ALSO INCLUDES A LISTING OF PATIENTS' RIGHTS AND RESPONSIBILITIES, DISCUSSIONS OF TYPICAL DIALYSIS AND TRANSPLANT MEDICATIONS, A GLOSSARY DEFINING KIDNEY TERMS AND A BIBLIOGRAPHY. IN SHORT, IT'S A DIRECTORY, A HANDBOOK, IF YOU WILL, OF EVERYTHING YOU WOULD EVER WANT TO KNOW ABOUT KIDNEY DISEASE SERVICE IN THE GEOGRAPHIC AREA ENCOMPASSED BY ESRD NETWORK #23. THIS HAS PROVEN TO BE A VERY POPULAR PUBLICATION AMONG THE KIDNEY POPULATION AND ONE THAT THE PATIENT ADVISORY COMMITTEE WOULD HOPE TO UPDATE AND RE-PUBLISH ON A BI-ANNUAL BASIS. IT WAS RESEARCHED, WRITTEN, AND PUBLISHED EXCLUSIVELY BY PATIENTS.

ABOUT A YEAR AGO, THE PATIENT ADVISORY COMMITTEE TOOK IT UPON ITSELF TO COMMUNICATE WITH ANOTHER COMMITTEE OF THE NETWORK, THE MEDICAL REVIEW BOARD, ABOUT PATIENT CONCERNS REGARDING THE DELIVERY OF KIDNEY CARE SERVICES IN THE NETWORK AREA. THE PATIENT POPULATION WAS CONCERNED THAT IT DID NOT HAVE ENOUGH KNOWLEDGE OF RENAL DISEASE OR TREATMENT OPTIONS AND THE VARIOUS MODALITIES FOR TREATING END STAGE RENAL DISEASE. I AM PLEASED TO TELL YOU THAT THE MEDICAL REVIEW BOARD OF ESRD NETWORK #23 SUBSEQUENTLY CONDUCTED A SURVEY OF THE PATIENT POPULATION AND CONFIRMED THAT MANY OF THE CONCERNS EXPRESSED IN THESE ORIGINAL COMMUNICATIONS FROM THE PATIENT ADVISORY COMMITTEE WERE TRUE.

AT THE CURRENT MOMENT, THE MEDICAL REVIEW BOARD OF THE ESRD NETWORK #23 HAS A MOST ACTIVE PROGRAM IN ASCERTAINING THAT STANDARDS FOR THE DELIVERY OF MEDICAL SERVICES IN THE AREA ARE ADHERED TO (BOTH DIALYSIS AND TRANSPLANT) AND THAT PATIENTS ARE IN FACT PROPERLY INFORMED SO AS TO BETTER PARTICIPATE IN THE FORMULATION OF THEIR OWN LONG TERM MEDICAL PLAN. I AM PLEASED TO SAY THIS PROGRAM WAS PRECIPITATED BY THE QUESTIONING ATTITUDE OF THE PATIENT ADVISORY COMMITTEE.

THE FINAL ELEMENT OF THE CURRENT PROGRAM OF THE PATIENT ADVISORY COMMITTEE OF ESRD NETWORK #23 CONCERNS A LEGISLATIVE INITIATIVE WHICH I AM PARTICULARLY PLEASED TO BRING BEFORE THIS SUB-COMMITTEE TODAY BECAUSE IT IS SOMETHING THAT WE HAVE RECENTLY COMMUNICATED TO THE HOUSES OF CONGRESS. AS MOST OF THE MEMBERS OF THE SUB-COMMITTEE I AM SURE ARE AWARE, MEDICARE NOW COVERS 80% OF THE MEDICAL COSTS FOR END STAGE RENAL DISEASE PATIENTS UP UNTIL 36 MONTHS AFTER KIDNEY TRANSPLANT. THIS INCLUDES HEMODIALYSIS, CONTINUOUS AMBULATORY PERITONEAL DIALYSIS (CAPD) AND SURGERY FOR KIDNEY TRANSPLANTATION, AS WELL AS THE ROUTINE MEDICAL MAINTENANCE AND HOSPITAL VISITS THAT ARE REQUIRED SUBSEQUENT TO THE KIDNEY TRANSPLANT. WE AND THE PATIENT ADVISORY COMMITTEE OF ESRD NETWORK #23 SUBMIT THAT THIS 36 MONTH CUT-OFF PROVISION CONTAINED IN THE LAW IS INEQUITABLE AND CONSTITUTES POTENTIALLY A FINANCIAL DISINCENTIVE FOR MANY PEOPLE TO RECEIVE A KIDNEY TRANSPLANT. WE ACCORDINGLY RECOMMEND THAT MEDICARE COVERAGE BE EXTENDED FROM THE CURRENT 36-MONTH STATUTORY LIMIT TO THE LIFE OF THE KIDNEY.

THE RATIONAL FOR THIS LEGISLATIVE CHANGE, TOGETHER WITH SOME STATISTICS ON KIDNEY TRANSPLANTATION AND ALSO SOME ESTIMATED COSTS OF WHAT THIS PROGRAM EXTENSION IS LIKELY TO COST ARE CONTAINED IN AN ISSUE PAPER WHICH IS ATTACHED TO MY TESTIMONY AND WHICH I WOULD LIKE TO BE MADE A PART OF THE RECORD OF THIS HEARING. WHILE EXTENDING THE MEDICARE INSURANCE COVERAGE BEYOND THE 36-MONTH BARRIER WILL COST THE COVERNMENT SOME ADDITIONAL FUNDS INITIALLY, IN THE LONG-RUN WE FEEL THAT SAVINGS CAN BE REALIZED BECAUSE PATIENTS WILL BE MORE INCLINED TO SEEK TRANSPLANTATION AS A MODALITY. WITH THE CURRENT 36-MONTH BARRIER IN PLACE, WE SUGGEST THAT THIS MIGHT BE A FINANCIAL DISINCENTIVE.

THIS PATIENT ADVISORY COMMITTEE PROGRAM HAS BEEN ADVANCED BY PATIENTS AND SUPPORTED BY THE NETWORK. HAD THE NETWORK NOT BEEN IN EXISTENCE, THERE WOULD IN FACT BE NO FORUM IN WHICH TO RAISE SUCH PATIENT CONCERNS AND ISSUES.

THIS, MR. CHAIRMAN AND MEMBERS OF THE SUB-COMMITTEE, CONCLUDES MY FORMAL STATEMENT. I WOULD BE PLEASED, TOGETHER WITH THE OTHER MEMBERS OF THIS PATIENT PANEL, TO ANSWER ANY QUESTIONS ON END STAGE RENAL DISEASE AND THE NETWORKS THAT YOU THINK YOU MIGHT WANT TO PLACE BEFORE US.

THANK YOU VERY MUCH.

REMOVING THE CURRENT 36-MONTH BARRIER TO CONTINUATION OF MEDICARE INSURANCE COVERAGE AFTER A KIDNEY TRANSPLANT

Background

Medicare, through Social Security Act Amendments, now covers 80% of the medical costs for End Stage Renal Disease patients up until 36 months after kidney transplant. This provision in the law covers 80% of the costs for hemodialysis, continuous ambulatory peritoneal dialysis and surgery for kidney transplantation, as well as the routine medical maintenance and hospital visits that are required subsequent to kidney transplant. This cut-off of Medicare benefits at the 36-month point is contained in P.L. 95-292 dated June 19, 1978. The specific reference is in Section 226 A,b,2 and reads as follows:

> Entitlement "shall end, in the case of an individual who receives a kidney transplant with the thirty-sixth month after the month in which such individual received such transplant, or in the case of an individual who has not received a kidney transplant and no longer requires a regular course of dialysis, with the twelth month after the month in which such course of dialysis is terminated."

Recommendation

The Patient Advisory Committee of End Stage Renal Disease Network #23 (which includes the District of Columbia, Northern Virginia, and the Southern Maryland) submits that this provision in the law which ends Medicare coverage at the 36-month point is inequitable and constitutes potentially a financial disincentive for many people to receive a kidney transplant. We recommend that Medicare coverage be extended from the current 36-month statutory limit to the life of the kidney.

Rationale

With Medicare and the Social Security Program already having invested vast amounts in many renal patients by way of years on dialysis and perhaps the cost of a kidney transplantation (or several), it makes little sense for Medicare to cease payments after 36 months because this tends only to denigrate the large investment which Medicare already has in these patients. Also, many patients with a transplanted kidney might not be able to bear the burden of the financial cost of medical maintenance on their own and would thus be inclined to take poorer care of themselves. Considering the large investment already made by Medicare in patients with a transplanted kidney, proper and adequate medical care should be almost as much a concern of Medicare as it is of the individual patient himself.

The philosophy of the federal Medicare program is to promote better and cheaper modalities for treating end stage renal disease. In the typical case (and assuming these options are medically possible), a patient is encouraged to dialyze at home (as opposed to in center dialysis) and ultimately to receive a kidney transplant. The Patient Advisory Committee of ESRD Network #23 suggests that this 36-month barrier articulated in P.L. 95-292 tends also to militate against this basic philosophy of Medicare.

We do not dismiss the important fact that expenses involved in all forms of treatment for kidney disease and its multiple related complications are prohibitive. At present, Medicare coverage is provided for 80% of the cost of dialysis and its related maintenance. Some patients have been treated by some form of dialysis since it became available. Improvements in technology and better knowledge of kidney disease promise these patients an ever-increasing lifespan. For many, it is the best, or only acceptable, form of treatment. We do not challenge their right of choice in mode of treatment.

There is a need, however, to establish an equity among all modes of treatment. The person with a kidney transplant is covered in the same manner as the dialysis patient for 36 months following a successful kidney transplant. At that time his coverage is terminated, but his expenses are not. We propose the extension of Medicare coverage to include the life of the kidney.

The initial first year expenses for a kidney transplant exceed those of the maintenance costs for the same time period with a form of dialysis. Following the first year of transplantation, however, these costs drop dramatically. But, they remain beyond the financial reach of many individuals. There are frequent lab services, expensive medication, and the preventive care so important to the transplant recipient who has his immune system suppressed. The body seeks to protect itself from the invasion of foreign matter, i.e. the kidney.

Protecting the kidney from rejection in this manner requires drug therapy. In turn, the body is vulnerable to other infections and diseases, requiring the patient to practice careful preventive medicine. Lab tests keep a check on the status of the kidney and anticipate potential problems. And there are complications. Among others, these include cataracts, lowered resistance, and bone demineralization that may require hip replacement.

In spite of these problems, a kidney transplant represents the best hope of reintegrating the person with end stage renal disease back into a more normal life. Physicians have said that while a machine may be able to maintain life, it can never equal the benefits obtained from a working organ. Loss of the kidney necessitates a return to a form of chronic treatment on dialysis.

The present termination of medical coverage for a kidney transplant after 36 months is a disincentive to the patient considering transplantation. Employers are reluctant to provide insurance coverage to a renal patient. Those patients who have entered the end stage renal disease program through disability are reluctant to reenter the job market and risk the loss of their entitlement to Medicare. While not able to handle full recovery status or return to their original type of employment, some transplant recipients could handle some form of partial recovery. They cannot, however, afford to lose their Medicare coverage. The government has a substantial investment in the person with kidney disease. It needs to encourage transplantation as an attractive alternative, whenever medically and emotionally feasible. The government needs to provide the security of continued Medicare coverage so that the transplant recipient has the confidence to attempt to return to some manner of self-reliance without fear of loss of vitally needed medical coverage.

Kidney Transplant Statistics

Since 1973, when Medicare first began to cover the costs of end stage renal disease, kidney transplants have been on the rise. The following table, which has been prepared from statistics secured from the U.S. Department of Health and Human Services presents the latest information that is available on kidney transplants for the Nation as a whole:

CALENDAR YEAR	TOTAL TRANSPLANTS	LIVING RELATED	CADAVERIC
1973	1,500	Unknown	Unknown
1974	3,179	Unknown	Unknown
1975	3,730	Unknown	Unknown
1976	3,175	911	2,264
1977	3,973	1,495	2,478
1978	3,949	1,172	2,777
1979	4,271	1,205	3,066
1980	4,630	1,270	3,360

While these statistics are impressive and show that surgical kidney transplants have risen dramatically in eight years (and in this time over 28,000 ESRD patients have been taken off the highly expensive dialysis regimen at least for a time), they do not indicate the number of persons living today in the United States with a successfully transplanted kidney. Those particular data for the nation as a whole are not available. Because of this gap in the current data colection system, we have tried instead to present as best we can the picture on the successful living kidney transplant population as we know it exists in Network #23 and then extrapolate that figure to approximate the nationwide statistic.

To present a comparable table on transplant activities for the metropolitan Washington, D. C. area and environs, the table below depicts comparable kidney transplant activity between the years 1977 and 1980 (the only years for which information is available) for ESRD Network #23:

CALENDAR YEAR	TOTAL TRANSPLANTS	LIVING RELATED	CADAVERIC
1977	95	45	50
1978	62	21	41
1979	79	28	51
1980	93	26	67

In these four years, there were 329 kidney transplants performed and, as of December 31, 1980, there were 149 of these patients who have a successful, still-living transplanted kidney. Of this 149 total, 51 (34%) have had their transplants more than 36 months and are, therefore, patients who would benefit by the legislative change we are recommending.

In an attempt to extrapolate the experience in Network #23 and apply that to the nation as a whole, we find that approximately 25% of all transplanted patients and their kidneys survive beyond the 36 month period. Utilizing the total number of transplants as listed in the first table above, there were performed since 1973 in this country a total of 28,407 kidney transplants. Assuming that 25% of those kidneys will still be functioning 36 months after the transplant (i.e. the Washington experience) , that would leave a total for the nation as a whole of 9,658 kidney transplants still functioning. Thus, there are, as best we can guess, about 9,700 patients living in this country with transplanted kidneys beyond the 36 month period, where Medicare would be picking up 80% of their expenses for routine medical maintenance and hospital visits.

Estimated Costs

The average kidney patient must report back to his renal transplant center (hospital) for extensive blood tests, urinalyses, and other medical checks, including a doctor's examination on the average of once a month. For patients who have no other medical complication, the cost of these monthly maintenance visits approximates $300-$600. On that basis, and merely extending the figures, the total cost for removing this 36 month barrier after transplant for current kidney patients would run somewhere in the magnitude of $28-$56 million per year (i.e. $300 X 12 [months X 9700 [patients X 80%). This amount can be compared to the cost of these patients remaining on hemodialysis for a year. The amount would be approximately $192,758,400.00 ($138 X 12 [treatments per month X 12 [months X 9,708 [patients . Thus, by these patients being and remaining transplanted, an estimated $136,758,400.00 to $164,758,400.00 per year would theoretically be saved.

As a secondary issue, the patient population would also advocate having the cost of monthly medications also covered by the Medicare insurance program. These routine medications for most kidney transplant patients run in the magnitude of $100-$200 for routine anti-rejection medications (such as imuran and prednizone). These costs are not now covered. Extending the same then arithmetic (i.e. $100 X 12 X 9700 X 80%), medications could cost an additional $9.0 to $19.0 million per year.

Patients on dialysis, however, have some of their medications covered by Medicare - albumin, inferon, decaducolium, antibiotics given intravenously or intermuscularly, and most emergency drugs.

For some transplant patients, their secondary insurance coverage will reimburse them for these medication costs, but not all renal transplant patients have a secondary carrier because they can't afford one or are not employed in a situation where such medical insurance is part of the normal benefits package.

In summary, the end stage renal disease patient population recommends that the current barrier which calls for Medicare insurance coverage to cease after 36 month after transplant be eliminated. Medical costs continue at a modest level for many of these patients beyond the 36 month period and our recommendation is that the insurance coverage be extended for the life of the kidney. The second point we would make is that Medicare coverage be extended to cover also the cost of routine medications which must be taken by patients with transplanted kidneys and which costs are currently excluded from excluded from payment by Medicare. Such changes, it seems to us, can be made by deleting and adding the appropriate language to Public Law 95-292. These legislative recommendations, while offered by ESRD Network #23, are also supported by other ESRD Networks around the country, as well as by the National Association of Patients on Hemodialysis and Transplantation and the American Society of Transplant Surgeons.

It must be stressed that we view these proposals as being not so much a further extension of a program, which we are fully aware is costing much more than the Congress and the Administration ever dreamed it would cost in the first instance, but rather an attempt to make more equitable the treatment of patients. Thus, our argument is one of equity; the extra costs involved are relatively minor compared to the total cost of the program and to what the costs would be if they remained on dialysis.

STATEMENT OF MR. WILLIAM BLACKTON, RESTON, VA.

Mr. BLACKTON. My name is Bill Blackton, and I thank the committee for allowing me to testify about my experience with end stage renal disease.

If I might summarize my history briefly, I first went on dialysis in March 1965, in Brooklyn, N.Y. Since then I have gone through 4 years of college. I had a kidney transplant for a year and a half. Most recently for the last 10 years I have worked in radio news; I now work on Capitol Hill. I must say it is a lot easier being over at that table than this one.

Senator BAUCUS. Where do you work?

Mr. BLACKTON. Mostly out of the Rayburn radio/TV gallery. I work for a company in Los Angeles that syndicates radio programs.

I would like to offer some purely personal comments about the ESRD program from my perspective as a home hemodialysis patient now. I live in Reston. And as a patient, of course, what concerns me the most is quality of care and particularly the quality of my care. However, I am also sensitive to what has to concern all of us, especially Congress, namely, the cost of that care. And I would like to talk about the relationship of the patient, himself or herself, to these two issues.

One of the points I would like to make is that self-care, patient's self-care, in other words, patients taking responsibility for themselves, knowing about their own illness, knowing how to treat that illness, is better care, in my experience; it is also cheaper care in the long run.

And if I had to summarize my statement in one sentence, I would urge the panel to, in whatever public policy method is available, to support the concept of self-patient care. For example, care given in a home dialysis setting or self-care in a center as well, which is also a practice in some areas of the country, make better use of existing staff members. That requires many people to take care of you.

In my experience, self-care patients feel better and do better medically. They require less hospitalization or medical treatment, generally.

It is also my experience that people who take care of themselves, who are encouraged to take care of themselves by the medical professionals around them, become more productive members of society. They become more emotionally independent as well of the machine in the process.

I am not qualified I think to speak to the specific public policy issues which are at hand here about the ESRD program; however, as I have said, what I would like to leave you with is that self-care is entirely possible, and it is practical, and it is preferred, in my opinion.

And I also would like to talk about the resources of the patients themselves. Dialysis, and any kind of treatment for end stage renal disease, is special because the patients learn quite a lot about themselves and about the treatment.

You have here a tremendous resource. We are just five or six people out of thousands who know a great deal about this program and a great deal about what makes them tick and what makes the program tick.

I urge the committee, Congress, and whoever is listening, to take advantage of that resource from organizations like NAPHT, from individiual people like ourselves, from patient advisory committees. Here is a group of people with tremendous experience that can be well utilized by Congress in cost cutting measures.

I think if the Government were to make it known to patients, well, look, we are in a financial bind. What do you have to say? It would be a valuable question to ask.

So, again, I thank the committee for allowing me to testify. And, as I say, it is a little different being at this table, but I am open to any questions.

Senator BAUCUS. Thank you very much.

[The prepared statement of William Blackton follows:]

STATEMENT OF WILLIAM BLACKTON

Mr. Chairman and members of the committee:

I'm honored to be a witness in the committee's hearings on the end stage renal disease program under Medicare. I'd like to make some purely personal comments about the program, from the perspective of 17 years on hemodialysis.

I started dialysis in march, 1965 in Brooklyn, New York. At that time, there were few dialysis machines and fewer doctors who knew about the treatment. Committees decided which ESRD patients would be allowed to go on dialysis--in other words, which ones would be allowed to live. I was one of the lucky ones.

From 1965 to 1969, I attended Columbia University in New York City. I dialyzed twice a week at the unit in Brooklyn. Back then, we were on the machine for 16 hours or so each time. I took the subway to the unit in the afternoon, slept their overnight, and returned to college the next morning. I graduated with a B.A. in psychology.

In the fall of '69, I made myself a candidate for a kidney transplant. In February, 1970 I received one from a person whose organs were donated after death. My new kidney performed well for a few months. Then, I had a bout of rejection which damaged the kidney's functioning. The transplant slowly deteriorated from then on, and it was finally removed in November, 1971.

I was actually relieved to go back on dialysis because I was able to function much better. In February, 1972 I began dialyzing at home. I've used that mode of treatment ever since.

When I have been on hemodialysis, I have always worked or attended school full-time. I'm currently a radio reporter working here in Washington for a program syndicator based in Los Angeles. Much of my time is spent on Capitol Hill. I dialyze on Sunday, Tuesday and Friday...at home...at night.

For me, and thousands like me, dialysis is simply a means to an end. I hope the committee doesn't lose sight of that fact in its study of the ESRD program. Dialysis can--and does--work. It has saved the lives of many thousands of productive Americans. Don't let the mountains of reports and figures and analyses overshadow the fact that what the ESRD program is about is a miracle. Had I taken ill a few years earlier, I wouldn't be here to speak to you this afternoon.

Having said that, I'd like to make a few comments about dialysis under Medicare. As a patient, the issue which concerns me most is quality of care. How does the patient feel, physically and emotionally? How well does he/she function? In my experience, the quality of care is not directly related to the amount of money spent for the care. The human factor is probably much more important. Unfortunately, it's much easier to read a balance sheet than it is to read the mind of a patient, nurse or doctor. There's no easy way to solve this dilemma. However, I believe the quality of care issue should be studied thoroughly. Patients who are knowledgeable and experienced at the art of dialysis should be consulted more often on this point.

Dialysis patients who are the least bit inquisitive learn a lot about their own care. I believe all patients should be encouraged to learn as much as possible about the treatment. Dialysis is one area of medicine where, after a while, the patient gets to see behind the medical mystique. Some doctors do encourage patients to learn about their disease and the treatment. Many still don't. I believe self-care can be an important cost-containment measure. I also believe self-care is better care.

I support policies which encourage patients to undertake self-care, either at a center or at home. For me, home dialysis is the optimal method of treatment. For someone else, it might not be. However, I think all patients should have the ability to make an informed choice about their own treatment. Unfortunately, I think many patients are not well-informed about the choices available to them...or about how well someone on dialysis can feel. If it hasn't already been done, I think it would be informative to survey ESRD patients, asking them what they think their options are and why they have chosen their form of treatment.

Here are my thoughts regarding some of the issues which have been discussed in regard to the ESRD program.

--I support the use of paid aides for home dialysis patients who need them. Total self-care is not possible for everyone, but each patient should become as independent as possible within their own limitations.

--I am firmly opposed to the re-use of dialyzers as a cost-cutting measure. I have yet to be shown that re-used dialyzers are as safe or efficient as new ones.

--I believe patients should have the right to choose a physician independent of their treatment setting.

--I'd like to see more research on reducing the cost of dialysis equipment and supplies. I would also support further development of portable artificial kidney machines.

I thank the Chairman for allowing me to testify before the committee. And may I take this opportunity, as one of the thousands of beneficiaries of the ESRD program, to say thank you for the chance to live.

STATEMENT OF BENJAMIN P. SCHOEN, WASHINGTON, D.C.

Mr. SCHOEN. My name is Benjamin P. Schoen. I am an in-facility dialysis patient. I have been on dialysis for 8½ years. I am presently an attorney with the Department of Justice in the Antitrust Division, and let me preface my remarks by saying that my comments with regard to the certificate of need process are mine and not necessarily those of the Antitrust Division. [Laughter.]

Although I must say I am hoping that they will be along the same lines.

Two issues seem to me to be inseparable: the level of competition in the provision of dialysis services, and the quality of care provided in outpatient dialysis facilities.

As you are aware, the number of dialysis machines or stations in any geographical area are controlled by a certificate of need procedure. The certificate of need process, however, has limited the number of available dialysis stations but has not necessarily limited costs or increased the quality of care in dialysis units.

A better system might be to eliminate the certificate of need requirement and to permit any qualified provider of services to open a dialysis facility, that is, to permit competition. Each dialysis unit would succeed or fail, depending on the quality of service provided. The Government would not pay any extra money, the payment for dialysis treatments being fixed; yet, the patient would receive a higher standard of care. Thus, open competition and the provision of dialysis services would foster patient care at the same level of Federal expenditures.

As the program is run now, there is no incentive for providers of dialysis services to give high quality care: the Federal payments for each dialysis is the same regardless of the quality of care provided.

Patients cannot move to other dialysis facilities if they are dissatisfied with their treatment, since the number of stations in most areas is limited. Thus, owners of outpatient dialysis facilities presently enjoy the benefits of a captive patient population without the incentive of competition to motivate improvements in the quality of care.

The only basis for dialysis units to compete with one another, remember, is the quality of care, cost not being a factor. On the other hand, without competition, owners of dialysis facilities have extraordinary motivation to squeeze the maximum profit from the fixed payment per treatment allowed by medicare.

Another reason why the certificate of need system should be eliminated is that the entire procedure tends to favor already established dialysis units. Those facilities have physicians and administrators already versed in the application/approval process, have members on the local ESRD network and have existing facilities which generally have space available for expansion. The certificate of need process thus tends to concentrate the dialysis industry.

This fact can be seen in the dominance of national medical care as a provider of dialysis services in many areas of the country.

Eliminating the certificate of need requirement would tend to minimize the influence of any one provider of services of dialysis facilities in any given geographic area, both on the ESRD network system and on the local HSA.

I would like to address briefly a few concerns I have about Federal regulations, and some of them have been addressed by the NAPHT's spokesman.

First of all, there is no requirement presently existing in Federal regulations regarding the availability of evening dialysis hours. As has already been mentioned, it is almost impossible to maintain a full-time job if dialysis is not provided during the evening or at some other alternative time when working people can take advantage of it.

Second, there are no regulations regarding the maximum number of patients per therapist. At the moment, there are basically nebulous requirements that there be therapists available, but no minimum or maximum regarding the number of therapists or even their qualifications.

And, third, the only regulation presently extant regarding the number of RN's in a particular unit is that there be one on the premises, not even necessarily on the floor. The only one who can provide a patient while he is on dialysis either medications or certain types of treatment are registered nurses. And, as a consequence, I would recommend that the number of patients per therapist be fixed as well as the number of patients per registered nurse.

I would like to thank the members of the subcommittee for your interest and concern, and I would be happy to answer any additional questions.

[The prepared statement of Benamin P. Schoen follows:]

STATEMENT
OF
BENJAMIN P. SCHOEN
TO THE
SUBCOMMITTEE ON HEALTH
OF THE
SENATE COMMITTEE ON FINANCE

Kidney failure (end stage renal disease) is the only catastrophic illness for which the federal government is the primary insurer. The End Stage Renal Disease ESRD program is thus the only extant national health insurance program. A study of the ESRD program thus will have serious implications about the validity and practicality of the concept of national health insurance, for the ESRD program is national health insurance in microcosm. This subcommittee has a unique opportunity to see federally funded health insurance at work and to determine whether it is operating efficiently and providing the best quality care for the money expended. As I will note in my remarks, the ESRD program has much room for improvement. I will direct my observations and recommendations to out-patient, in center dialysis.

First let me note that I am 35 years old and an attorney with the Antitrust Division of the Department of Justice. I have been on dialysis eight and one-half years. During the nine and one-half years I have been with the Department of Justice, I have had occasion to do a significant amount of traveling throughout the United States. My comments are thus based on a broad range of experience and are not confined to any local problem in the Washington, D.C. metropolitan area.

Two issues seem to me to be inseparable: the level of competition in the provision of dialysis services and the quality of care provided in out-patient dialysis facilities. At present, the number of dialysis machines (i.e., stations) in any geographic area are controlled by a "certificate of need" procedure by which local Health Service Administrations (HSAs) determine how many dialysis stations are "needed." If the HSA determines there is a "need" for more stations, applications can be submitted by anyone offering to provide the additional dialysis facilities which would meet the need determined to exist by the local HSA.

At present, the "certificate of need" process has limited the number of available dialysis stations but has not necessarily limited costs or increased the quality of care in dialysis units. A better system might be to eliminate the "need" requirement and to permit any qualified provider of services to open a dialysis facility -- i.e., to permit competition. Each dialysis unit would succeed or fail depending on the quality of service provided. If a dialysis unit has less trained personnel, outdated equipment and no individualized treatment, it will lose patients to other facilities that have superior personnel, equipment and treatment. The government would not pay any extra money, the payment for dialysis treatments being fixed, yet the patient would receive a higher standard of care. The financial risk if a dialysis unit fails to earn a reasonable return would -- and should -- be borne by the provider of dialysis services -- not the government. Thus, open competition in the provision of dialysis services would foster quality patient care at the same level of federal expeditures.

As the program is run now, there is no incentive for the providers of dialysis services to give high quality care: the federal payment for each dialysis is the same regardless of the quality of care provided. Patients cannot move to other dialysis facilities if they are dissatisfied with their treatment, since the number of stations in most areas is limited. Thus, owners of outpatient dialysis facilities presently enjoy the benefits of a captive patient population without the incentive of competition to movitate improvements in the quality of care. The only basis for dialysis units to compete with one another, remember, is quality of care, cost not being a factor. On the other hand, without competition, owners of dialysis facilities have extraordinary motivation to squeeze the maximum profit from the fixed payment per treatment allowed by Medicare. The results of competition on the quality of care provided dialysis patients can be seen vividly in the Washington, D.C. area. National Medical Care was moved to upgrade the equipment in its largest dialysis facility in this area only when a new, competing unit opened at Holy Cross Hospital which provided what numerous patients believed to be superior care. Approximately thirty patients opted to go to the competing Holy Cross dialysis unit. The dialysis unit that these thirty or so patients left is now modernizing its dialysis equipment. Ultimately, the patients in both facilities will be better off.1/

1/ It should be noted that, because of the certificate of need process, Holy Cross was only permitted six dialysis stations. Had more been authorized, it is likely additional patients would have transferred.

Another reason why the "certificate of need" system should be eliminated is that the entire procedure tends to favor already established dialysis units. Those facilities have physicians and administrators already versed in the application/approval process, have members on the local ESRD network and have existing facilities which generally have space available for expansion. The "certificate of need" process thus tends to concentrate the dialysis industry. This fact can be seen in the dominance of National Medical Care as a provider of dialysis services in many areas of the country. Eliminating the "certificate of need" requirement would tend to minimize the influence of any one provider of services of dialysis facilities in any given geographic area, both on the ESRD network system and on the local HSA.

Let me address another area of concern: federal regulations regarding dialysis facilities. While the regulations recommend that dialysis facilities provide evening hours so that patients who work can have their treatments in the evening, they do not mandate the providing of such evening treatments. This failure to require evening treatments is counterproductive, primarily because it discourages rehabilitation of patients. If, as is the case in numerous areas throughout the country, one can only dialyze between the hours of 7 a.m. and 6 p.m., it is impossible to hold a full-time job. The aim of dialysis should not only be to sustain life, but also to permit those able to work to lead useful meaningful lives. That goal cannot be accomplished if the patient has no other choice but to quit work to obtain his or her treatment. Evening treatments should be available to any dialysis patient who needs them in order to remain employed, and the federal regulations should be amended to require such evening hours.[2/]

Federal regulations also fail to specify the maximum number of patients any therapist should be responsible for. It is clear to me that having one therapist responsible at any given time for five patients is only marginally adequate. After all, patients lives are at stake during dialysis: sudden and sharp blood pressure drops, severe muscle cramps and heart failure due to the strain of dialysis can occur, all of which require immediate attention by competent personnel. Yet, in many centers, that ratio is utilized. I would recommend that the federal regulations require that dialysis therapists be responsible for no more than three patients at any given time. Additionally, I suggest that the regulations require one registered nurse -- who, of course counts, as well, as a therapist -- for each six patients. Only nurses, not therapists, can administer medications patients need while on dialysis. Thus, in a dialysis facility with 12 patients, the regulations should require four therapists, of whom two would be R.N.s.

2/ A corollary effect of lack of evening hours is that the government does not receive the benefit of taxes which would be paid by dialysis patients who would, but cannot, work due to the lack of evening treatments. Although it is unlikely that the federal government could recoup all its expenditures on dialysis through tax receipts from working dialysis patients, it can recoup some of them. In these days of tight budgets and fiscal restraint, that is a worthwhile objective.

Physician access to out-patient dialysis facilities is another area where federal regulations fail to protect patients' welfare. When a patient goes to many dialysis facilities, he must use for his dialysis care the physicians who own or operate the facility. Many dialysis facilities do not have "open" units where any doctor can visit his or her patients. Again, patients should be permitted to have the doctor of their choice see them at their dialysis facility -- whether he owns the dialysis unit or not.

Let me touch on one other area of concern in the limited time available: the enforcement of existing federal regulations. I have tried, over the years, to identify the federal agency or bureau responsible for enforcing the regulations. It has been a hopeless task. No one within HHS will accept responsiblity for implementing the regulations or disciplining those who disobey or contravene them. Indeed, it is difficult even to determine the penalty for disregarding the regulations. Some procedure or mechanism must be established providing for direct patient access to lodge complaints about dialysis services. And some section or bureau must be identified which can remedy wrongs and enforce the regulations -- and which has specific, understandable, unequivocal authority to act on behalf of the patient, and the government. Otherwise, the regulations have no meaning,to the patient or the provider of services.

Before I conclude my remarks I would like to submit two documents for inclusion in the record. One is a letter to former Congressman Newton Steers in July 1977, discussing in detail problems in the ESRD program as presently constituted. The other is a letter to the editor of the Washington Post which I wrote in April 1978, which deals with home dialysis and the need for evening dialysis treatments. I believe you will find both of these informative.

I would like to thank the members of this subcommittee for your interest and concern. I will be happy to answer any of your questions or make myself available in the future if you seek additional time or information from me.

DATED: September 28, 1981

5500 Friendship Boulevard
Apartment 1714N
Chevy Chase, Maryland 20015

July 20, 1977

Honorable Newton I. Steers
U. S. House of Representatives
Washington, D.C. 20510

Dear Congressman Steers:

I am a dialysis patient who seeks your help in solving a local problem which has national implications (see attached article). It involves the medical care provided by privately-owned dialysis units, federal oversight and payment for dialysis and the present conflict of interest of doctors who own dialysis facilities.

Dialysis treatment -- the use of artificial kidney machines to cleanse the blood of wastes, usually three times a week, four to five hours per treatment -- is becoming big business in the United States. The federal government, through Medicare, presently pays 80% of all medical costs of dialysis (treatments plus doctor bills and related hospital, medical and laboratory costs); the federal government paid almost $500 million last year, and it is estimated dialysis costs will be $1 billion a year by 1980.

It is thus imperative that the Medicare program be run efficiently in order to reduce costs. It is also imperative that privately-owned dialysis facilities and their owners (usually doctors) be required to provide -- in return for the vast sums of money they receive -- high quality medical care. Presently, the HEW rules and regulations dealing with dialysis facilities neither demand efficiently-run dialysis units nor high quality medical care. In addition, there appears to be an inherent medical conflict of interest in doctors owning dialysis facilities -- they have a financial interest in cutting costs to maximize profits. This can only be done at the expense of patients. Also, doctor/owners have little or no incentive to encourage kidney transplants since a successful transplant means one less dialysis patient. I will address this question later.

With respect to the efficiency and medical care questions, a few observations:

1. In present HEW regulations, there are no qualifications for dialysis therapists (a therapist is the person directly responsible for patient care on a minute-to-minute basis). Anyone

can be a therapist; there are no educational prerequisites. In my dialysis unit (Metropolitan Washington D.C. Renal Dialysis Unit in Bethesda, Maryland), the doctors who own the unit have hired high school graduates with no previous medical training to be therapists. Some of these people were under 20 years old when hired; yet, they were directly responsible for the lives of patients at the facility. Why do the doctors hire untrained personnel? Because it is cheaper. Some dialysis facilities (state-owned or in-hospital) use only registered nurses for most patient care.

In my unit, the doctors have told the therapists that they are "unskilled labor" and, therefore, are easily replaceable. Thus, the doctor/owners pay low wages (under $8,000 a year); as a consequence, there is a high therapist turnover rate. Once the therapists become skilled, they leave for better paying units (or just leave). From conversations I have had with therapists (who in turn have spoken to the doctor/owners and their representatives), the doctor/owners do not care about high turnover because it means lower average salaries and, hence, higher profits. Patient care seems to be a low priority item. I have had personal contact with two of the doctor/owners (there are four in all), and they do not seem to share my concern. I will be happy to provide details, but the incidents are too lengthy to describe here.

2. HEW regulations fail to provide certain health and safety precautions. If HEW does not require them, the doctors will not voluntarily implement them. Before giving a few examples, let me explain why the doctors will not voluntarily implement them.

Medicare pays a flat fee to dialysis units for each dialysis: $138. This is regardless of cost. Dialysis facility owners are under no obligation to provide cost/profit data. Consequently, if doctors owning dialysis units can cut their costs by, say, using cheaper artificial kidneys or kidney machines or clamps or stethescopes or -- as is the case in my dialysis unit -- cheaper bandaids (which patients need after dialysis) they will. Each dollar saved is a dollar greater profit. So, there is a built-in incentive to cut costs. This relates back to why the doctors hire untrained personnel and prefer high turnover of therapists: it lowers costs. In my dialysis unit in Bethesda, there are 12 or 13 therapists working on my shift. A large majority have been there less than two years; a significant percentage, less than one. By contrast, therapists and nurses in the two state-owned units -- which pay at least $2,000 a year higher starting salaries -- have an average time in job of almost five years. (Which facility do you think would provide superior medical treatment?)

What health measures do the doctors fail to utilize (and HEW fail to require)? Failure to isolate hepatitis-carrying patients. */ Failure to use uniform, rigid sterile techniques to prevent infections and/or hepatitis. Lack of individualized patient treatment (*e.g.*, in my unit, all patients use the same type of artificial kidney -- the part of the machine that actually cleanses the blood. But there are three different *types* of kidneys (and numerous brands for each type) some of which might be preferable for different patients. We do not have a choice). **/ These are but a few issues.

In addition, HEW regulations do not provide for *unannounced* inspections of the dialysis facilities. Thus, inspectors do not see how the unit operates during its normal work day. In my unit in Bethesda, there is dirt never seen by inspectors, only by therapists and patients. The last time an *announced* inspection occurred, the doctor/owners paid the therapists overtime to clean up the unit. The inspectors then saw a nice, clean facility. HEW regulations require a once-a-year announced inspection -- dirt can accumulate for 12 months with no one to monitor the cleanliness and sanitariness of the unit.

HEW regulations also say nothing about the length of the work day. In my unit, therapists work 12-hour days. That is a long time for people to remain alert and responsive -- particularly when lives are at stake. The doctor/owners implemented the 12-hour day to save money. The therapists last year were asked -- no, told -- to work 12-hour days instead of the 10-hour days they had been working -- for the *same* pay. Also, the same number of therapists, working a 12-hour day, can now dialyze more patients than before, so the doctors get more dialyses per salary dollar spent. Twelve hours, in my opinion,

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*/ Contracting and spreading of hepatitis is a very real concern in all dialysis units. Patients can be "carriers" of the hepatitis virus. A recent study showed that, in units where hepatitis-carrying patients were *not* isolated, the incidence of hepatitis was almost twice as high for both patients and therapists as in units which isolated hepatitis-carrying patients.

**/ This is all very technical and difficult to summarize in a letter. I will be happy to go into detail as to the medical significance of all of this at your convenience.

is too long for people to work who have such vital responsibilities. It favors haste over thoroughness, encourages short cut measures (e.g., failure to use good sterile techniques -- it is too time consuming) and results in fatigue at times when alertness is crucial.

HEW regulations say too little about the patient/staff ratio. In my unit, at any given moment, two therapists are responsible for ten patients. Given the nature of dialysis patients and dialysis treatments, this is inadequate. Emergencies, blood pressure drops, cramps, nausea are common occurrences. Three therapists per ten patients should be required.

3. The situation in my dialysis facility is becoming more acute. The doctor/owners rarely, if ever, see the patients -- they hire "moon-lighting" nephrologists to see the patients. Of course, they (the owners) get the $200/patient/month fee Medicare pays for patient care -- not the doctors who actually provide the oversight. The doctor/owners are also considering switching to an artificial kidney manufactured by a subsidiary of their parent company. */ Obviously, it is more profitable to buy from your subsidiary than an outside manufacturer. Whether it is better medical care for the patient is another story. Right now, no one can prevent such a switch, even if the new artificial kidneys are less effective and less efficient.

The therapists at my unit have formed a union (in self-defense). I cannot blame them. They are paid the lowest salaries (or near the lowest) of any dialysis therapists in Maryland. On the other hand, what do patients do if they decide to strike? The doctor/owners know the therapists cannot, in good conscience, strike, so they do not really have to compromise in the salary talks.

I could name many other problems, but they are too numerous to itemize here. Suffice it to say they are serious problems

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*/ National Medicare Care (NMC) is the parent company. They wholly own BioMedical Applications, which in turn owns my dialysis facility (as well as the vast majority of all privately-owned dialysis units in the country). NMC also wholly-owns Erika, a manufacturer of dialysis equipment. The doctor/owners generally are shareholders in the BioMedical Applications subsidiary that owns the unit, so they are owners of the unit. In addition, the doctor/owners often have management contracts with NMC which provide "incentive" bonuses based on the profitability of the facility they operate. Another incentive to cut costs.

which reflect on the concern of the doctor/owners for the patients' health and safety, inadequate health and safety precautions and failure of the doctor/owners to meet requirements set forth in the Code of Federal Regulations for the running of dialysis facilities.

4. The medical conflict of interest question is deserving of attention. First, doctors who own dialysis units have a vested interest in keeping patients on dialysis, rather than encouraging kidney transplants. Second, their financial interest in making profits conflicts with their medical judgment as to the best patient care. Can (will) doctors favor better medical care if it means a reduction in profits? Should they have to make that choice? This whole area of conflict of interest has not previously been explored.

What recommendations do I have? They can be divided into two separate categories: (1) those concerning my particular dialysis unit and (2) those involving the entire program.

With respect to the local Bethesda facility:

A.. An "investigation" by you through your staff would be of immense help. Such an investigation would present a microcosm of the entire system (albeit perhaps at its worst) and possibly give the doctor/owners incentive to rethink their attitudes. The investigation could include unannounced visits, discussions, with patients (outside the unit -- many patients are scared to voice their opinions in the dialysis facility itself), discussions with therapists (again, outside the unit), perhaps a visit by you personally, if that is at all feasible.

The doctors fear publicity. I know that for a fact (as a matter of interest, when the Montgomery County water shortage occurred, an NBC camera crew appeared at the Bethesda facility to cover the emergency water supply being utilized by the unit. The doctors forbade the dialysis therapists from talking to the camera crew). Thus, your intervention would provide exactly what the doctors fear most -- the publicity of an investigation of their dialysis facility. */

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*/ It should be noted that these doctors own two other units in the area: one, in Fairfax, Virginia, the other in S.E. Washington, D.C. Another facility, at DuPont Circle, is run by different doctors, but is owned by Bio Medical Applications (i.e., NMC, again). The one other private unit in the metropolitan area is in Camp Springs, Maryland -- 35 miles from my residence. A patient has little choice, then, where to be dialyzed or by whom. This is what makes the problem so critical.

B. Press coverage would also shed light -- and heat -- on the doctor/owners. Once the issues come to light with your intervention, the press may itself wish to investigate the program. A "60 Minutes" program on this whole situation would be devastating. You could, more easily than I, attract or solicit such coverage.

C. An attempt to impose on the facility a strict interpretation of the present federal regulations relating to dialysis (See 41 F.R. 22503 et. seq., June 3, 1976, or 20 C.F.R. §405.1031 et. seq.). This would, of course, have to be done through HEW, which implements the regulations. They have not been particularly responsive to patient needs up to now and will have to defend their record in this area, so their cooperation may not be forthcoming (that is part of the problem). However, once Congressional involvement occurs or they anticipate publicity with regard to their past and future actions, they might be willing to take more positive action. Miracles do happen.

These are just a few possible recommendations for the local situation. I have others. With regard to the general problems -- and the need for long-term solutions -- a few suggestions:

1. Revision of HEW regulations to tighten health, safety and sanitary requirements at dialysis units. I can make detailed recommendations in person -- they are too numerous (again) to put in this letter, but they relate to some of the problems outlined above.

2. Require unannounced inspections at least twice a year by impartial inspectors.

3. Devise a cost-related payment system for dialysis, perhaps a cost plus fixed-fee structure. Require financial data from the dialysis facilities. */ Such measures would reduce federal costs and remove the conflict between medical judgment and financial gain.

4. Investigate HEW licensing practices for new dialysis facilities. National Medical Care seems to have a near monopoly on privately-owned facilities.

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*/ My unit grosses well over $3 million a year for treatments and doctor fees. Profits could run as high as three quarters of a million dollars this unit alone based on my rough calculations. Of course, there is no financial data presently available for such an accounting.

5. Consolidate the HEW offices responsible for overseeing this program. Give them some sanctions to force the dialysis units to provide the safe, sanitary environment they should provide. And put people who are familiar with dialysis in positions of responsibility. Perhaps even some patients.

These are some of the problems and recommended solutions. The area is a complex one and cannot be thoroughly analyzed in a letter. The issues I have mentioned are only a few of many I could have discussed. This letter was meant mainly as a starting point, an outline of some of the key issues. I will be happy to provide additional information, personal testimony, anything you need to expedite matters.

Thank you for your interest and cooperation.

Sincerely yours,

Benjamin P. Schoen, Esquire

Same letter sent to:
Senator Charles McC. Mathias
Congressman Dan Rostenkowski

5500 Friendship Blvd.
Apt. 1714 N
Chevy Chase, Maryland 20015

April 7, 1978

Editor
The Washington Post
1150 15th Street, N.W.
Washington, D. C. 20071

Re: Editorial "Dialysis at Home"

Dear Sir:

The reference to dialysis patients in your editorial "Dialysis at Home" (April 3, 1978), as "terminally ill" is both uninformed and dangerously misleading. Dialysis patients can, and often do, lead productive and meaningful lives; they are no more "terminally ill" than the editors of the Post. During the 5 years I have been on dialysis, I have met dentists, lawyers, doctors and engineers as well as housewives with families. I myself work full-time as an attorney with the Department of Justice. I have met no patient who considers himself "terminally ill" in the traditional sense that term is used. Dialysis patients expect, much as you do, and with almost as great reason, that we will be here tomorrow, next week and next year-although our expectations are tempered by the reality of our situation. Your editorial reference leads the public to believe that dialysis is just a method of prolonging doomed and, inferentially, useless lives. By fostering that erroneous belief, you do us, and the public whose money is spent to finance the cost of dialysis, an injustice.

About home dialysis, two points need to be made. First, home dialysis is not for everyone. As a single person who works more than 40 hours a week and who spends an additional 15 hours a week on dialysis (Mon. - Wed. - Fri., 6-11), I presently have little free time to spend cleaning and setting up the kidney machine, ordering supplies, keeping records and filing the requisite forms - all necessary for home dialysis. Second, home dialysis requires absolute confidence in the capability and reliability of the person responsible for your safety while on the machine. Dialysis patients can't afford to miss one treatment - the consequences could be fatal. At the moment, most home patients are cared for by relatives: not all of us have family available or capable of handling the responsibilities of home treatment (I might note here that the reason home dialysis patients seemingly have a lower mortality rate than those in centers is that, in general, only the healthier patients are eligible for home care).

Finally, the dialysis program, as presently administered, does not stress rehabilitation to the extent it should. Many dialysis units around the country (and in my job have had occasion to visit quite a few) do not provide hours for dialysis in the evenings. Without such evening hours, it becomes almost impossible for patients to continue to work. This unavailability of evening hours occurs in spite of and in disregard of a federal regulation recommending (but, unfortunately, not mandating) that dialysis centers provide hours which would enable working patients to be dialyzed in their non-working hours. Despite numerous efforts, I have been unable to provoke the responsible federal agencies to implement this regulation. Both the patient and the government benefit if patients can continue to work: Not only is it psychologically beneficial to patients, but it also enables the government to recoup some of its expenditures on the dialysis program through taxes paid by rehabilitated, employed patients. After all, the goal of the dialysis program should not be to sustain life, but to permit active, productive lives.

If the Post is interested in minimizing costs and helping patients, investigating the government's failure to require centers to provide evening dialysis hours - with the consequent prejudice against those who want to continue working - would be a worthwhile starting point.

Yours truly,

Benjamin P. Schoen, Esquire
739-4117 (work)
657-8734 (home)

A4 The Montgomery Journal, Wednesday, September 23, 1981

Man Claims Dialysis Machine Forced Air Into His Bloodstream

By Les Brindley
Journal Staff Writer

A man who suffered partial paralysis and brain damage when air was pumped into his bloodstream during kidney dialysis treatment six years ago is suing the dialysis machine's manufacturers, the Bethesda treatment center and several others for $2.05 million.

The suit, filed by Edward P. Hadley and his wife Gladys, both of St. Michaels, Md., will go to trial Nov. 23, according to attorneys in the case.

The suit charges that Hadley suffered near complete paralysis on his right side, including his right arm and hand, and brain damage, including memory impairment, thinking impairment, impaired equalibrium and irritability.

The incident occurred, according to the suit, on July 9, 1975, when Hadley was undergoing treatment at a renal dialysis center on 4905 Del Ray Ave., in Bethesda. The center is owned by Bio-Medical Applications of Washington, Inc.

Hadley suffered an embolism when air leaked into the dialysis machine's tubing and was pumped into his bloodstream, according to the suit.

Hadley was rushed to Georgetown University hospital, which had referred him to the dialysis center in the first place. He remained in the hospital for over a month, according to the suit, and ran up more than $30,000 in bills.

Bio-Medical and the hospital are listed as defendants in the suit. Also listed are: Sarns, Inc., a Michigan firm that manufactured the blood pump; Travenol Labs, Inc., the firm that manufactured the dialysis machine and the tubing; Erika Distributers, Inc., the company that distributed the equipment; and four doctors affiliated with Bio-Medical.

The suit seeks $2 million for the incident itself and $50,000 for the damage it caused to Hadley's marriage.

Hadley charges that Sarns and Travenol were negligent in designing the equipment. The blood pump built by Sarns was "dangerous and defective," the suit charges. It says the tubing built by Travenol was of improper length, which allowed it to be punctured by part of the dialysis machinery.

The suit also charges that the two firms were negligent because they did not build a "fail-safe" system into the dialysis machine that would shut off the machine if air were detected in the tubing.

Bio-Medical, according to the suit, failed to warn Hadley of the defective pump, failed to have a fail-safe device in the equipment, failed to properly monitor the procedure for air bubbles and failed to have qualified doctors supervise the treatment.

The hospital was included in the suit because it referred Hadley to the dialysis center and because it receives referral fees from Bio-Medical.

Because of the financial arrangement between the two, the hospital also was hit with the same negligance charges as Bio-Medical.

The suit was filed on July 7, 1978.

Senator DURENBERGER. Thank you all very much for the concern that brings you here today.

Let me ask a general question of all three of you. Suppose we change the reimbursement system, as some have proposed, for medicare so that we use a voucher system. Let's say I gave you a voucher worth $15,000, or whatever the appropriate figure was, and told you to make your choice of treatment in the marketplace. How would that work and what effect would it have on providers?

Mr. BLACKTON. I have thought about it briefly before. I am not going into it in detail, but I think there might be a problem with new patients with vouchers because a new patient doesn't know anything about the treatment; he doesn't know what is good and what is bad.

Somebody like myself or the people here, as I mentioned in my statement, we are pretty sophisticated at what is good treatment and what is not. We know. But a new person doesn't have that experience. So that would cause me problems.

But I think the idea has promise, that kind of idea. The ability to choose, in other words, where you are dialyzed. Giving the patients some power as it were in the system.

Mr. SCHOEN. If I can add, there are two factors that I see involved in that. One is choosing facilities, for example, in a case like myself where I am an outpatient, among dialysis facilities, and that would be somewhat tied with the certificate of need process. If there are other dialysis facilities available, which until recently, for example, in this area there were not—there was one provider of service in almost every unit in the area—it would provide a tremendous incentive for units to provide better care.

But as has been mentioned previously, not all patients have a choice in the modality of treatment that is available. For example, I am single. It would be virtually impossible to go to a home dialysis environment. I think that has to be taken into consideration. The vouchers may not be able to be used to determine a particular modality of treatment.

Senator DURENBERGER. I have heard several times about the lack of mediating structures in the country. I know you travel a great deal, and I take it you must put considerable effort into finding out what services and facilities might be available in various parts of the country. How do you provide yourself with that kind of information?

Mr. SCHOEN. A tremendous amount of work. I have found in a number of areas, for example, I had a case in Atlanta recently, and I must have called five or six units down there, and they are either—do not have evening hours or they are virtually booked up. It is the first time I have encountered that. But, again, to the problem of certificate of need down there, I do not know what would happen if that wasn't available.

But it is almost like making hotel reservations: finding a unit in the area; trying to find out about the type of service provided at that unit. There are three kinds of dialyzers, for example, finding out which ones are used there.

If I could be permitted one comment about a slightly related subject, and that is, someone was mentioning earlier about a focal point for patient complaints and things of that sort. I have had occasion, numerous occasions, to try to locate somebody within HHS who has responsibility, for example, for going into a dialysis unit and saying, "Look, you've got one therapist for 40 patients. You can't do that." And to close the unit down if need be.

I can tell you, I don't know of any person, entity, bureau, section that has responsibility to do that or to take any action with respect to a particular dialysis unit that may be violating regulations that are in existence today.

Senator DURENBERGER. Mr. Blackton, may I ask you again, with an apology for not having heard your statement in full, what your advice to us is in terms of how we might increase the use and availability of home dialysis?

I just heard the single man here on your right discuss one of the problems, but obviously there are alternatives to that in this society. [Laughter.]

What are some of the problems that you face as a home dialysis patient, and what kind of disincentives for home dialysis have you experienced?

Mr. BLACKTON. First of all, I would like to say I am a single person as well, at the risk of opening up a whole can of worms. [Laughter.]

Senator BAUCUS. You have opened them.

Mr. BLACKTON. I have opened it.

Mr. BAUER. Maybe I can speak to that while Bill thinks about his answer.

I was a home patient for 5 years. I am married, and my wife and I were dialysis partners for 5 years.

The pressures that that kind of sickness and those kinds of responsibilities can bring to a relationship as intimate as a marriage are fantastic.

My wife and I have a daughter who is now grown, but at the time that end stage renal disease hit me was 16 years old, a time when a youngster really needs the attention of a mother and a father. We had to make her part of this, and we had to make her understand that while I was ill, it was still a very manageable thing. So we tried to keep her as aware of my problem and yet keep the home life as normal as possible. A pretty thin line to walk. But we have made it and I am sure others can do it, too.

Mr. BLACKTON. Let me add my comments to Mr. Bauer's and then I will get to myself. I also know several families who have coped successfully with home dialysis. I think the ability to go home in many cases enhances family life, and it makes it possible, where it is not as possible if the patient has to go to a unit which sometimes may be far away.

As to myself, I personally have not had that much trouble with adapting to home dialysis. It is something I do, and that is about the size of it in my life.

At one point, I had a job which started in the afternoon. I had to get up very early to go on dialysis, and found myself falling asleep in the middle, so I asked a young lady to come over for an hour while I slept. And this was a long time ago and predated the so-called paid aide program. But that did enable me to get a little bit of rest while I was on the machine and to keep to that schedule and go to my job in the afternoon.

So I would support the concept of paid aides, in case they did not have a person to stay by me.

Senator **Durenberger**. Thank you.

Senator Baucus?

Senator **Baucus**. Thank you, Mr. Chairman. Mr. Blackton, as I listened to you, I seem to understand from what you are saying, more people presently on dialysis at centers could be shifted to have dialysis. Is that a correct inference?

Mr. **Blackton**. Completely off the top of my head, I think yes. I never answered Senator Durenberger on that as well: How can we increase the number of home dialysis patients?

I think it might be interesting, as Miss Davis mentioned earlier, the percentage of home dialysis patients varies from network to network. That has always astounded me as to why that should be. I think it might be interesting to find that out if we are talking about studies and data.

Anyway, is it possible to put more people on home dialysis? Yes, I think so if they were encouraged to. But I don't think that is the entire answer, not just to say, well, everybody go on home dialysis.

Senator **Baucus**. Right.

Mr. **Blackton**. One reason why I used the term "self-care" in my statement instead of "home dialysis" is because I think that is an alternative. Many people do not have the ability to go home because of all the reasons that have been mentioned earlier.

However, in the setting of a unit, cost can be reduced, and patients can become much more independent by taking care of themselves, as long as they have the cacoon or the unit to go to, the facility.

Senator **Baucus**. I do not understand what the disincentives are of some shift to home dialysis. I understand single people have a harder time. I can understand that problem. But what other institutional problems or other practical problems or practical reasons are there which discourage more people from going to home dialysis?

Mr. **Blackton**. I think Miss Davis went into this before about the extra costs in terms of water and electric bills, the lack of facility, the need to convert plumbing, the lack of space. These are financial disincentives. I am not sure about the program-related disincentives because I am not that familiar with everybody's situation. However, those are certainly disincentives in some cases.

Mr. **Bauer**. You have got to have an emotional situation at home that is going to accept this. You have got to have a physical structure that you live in that can accept this. Some people just cannot accommodate those kinds of things.

Senator **Baucus**. That leads to the question that Senator Durenberger asked and that is the voucher system. The question in my mind is how do we accept the amount of the voucher? Is it that we give a certain voucher with a certain amount to home dialysis patients and another voucher with a greater amount to those who are not on home dialysis, and how that amount is set? Maybe that is a way to encourage more people to go to home dialysis, but that sounds like a fairly arbitrary way to encourage home dialysis.

I am just curious again what reaction you might have to the voucher system with that question in mind, and, second, how often and under what circumstances do you think the amount of the vouchers should be reviewed.

Mr. BAUER. Should be reviewed?

Senator BAUCUS. Yes; because any voucher system, to me, to some degree has certain caps built into it, that is, a certain fixed amount, like a free check.

Mr. BLACKTON. Yes. Well, there are different kinds of vouchers, too, I believe. But it is a tough question. It is a very good question, but I don't think I am really capable of answering except from my personal feeling. I think that, as I said before, it is an interesting solution but I don't think it will be the entire solution, because new patients would not be able to use it with knowledge.

As to the amount, it would have to vary with different parts of the country. It would be a very difficult question that you would have to analyze in detail, but I think it does have promise.

Mr. SCHOEN. Can I make a point as far as home dialysis goes as well, and that is something—I am not sure which speaker touched on it—but that has to do with the control right now of the present providers of the services. Many patients, particularly new patients, rely on the—we usually do start out I think in an in-center dialysis facility and eventually move to home dialysis. We have to rely on the providers of the service to give them the information necessary to make those kinds of choices.

Right now, given the present system, there is very little incentive for the owners of the dialysis facilities to encourage people to leave, because each time someone leaves, we are talking about a net loss in revenue of $500 a week. That is a tremendous disincentive to promote home dialysis as an alternative, as it is with, for example, CAPD. And I think that is one fact that has to be considered, and that is, how patients become aware of alternative modes and how they are being, or who has the best incentive to inform them of what the appropriate alternative mode might be.

Providers of the service right now who—this also ties in with, for example, the access of physicians to facilities. The owners right now of most free standing units have exclusive jurisdiction of those facilities. You cannot just have your private physician come in.

Given that fact, whatever information is going to be given is being given by the person who is benefiting most by your being in that facility.

Senator BAUCUS. I will end up by Mr. Blackton's point. All of you are probably most knowledgeable about this program than anybody else. What is it we should be asking? What is it that you want? What is irritating and gets under your skin a little bit about the program that you think we should know about that you haven't already mentioned. Is there anything else?

Mr. BLACKTON. Well, as I mentioned before about the percentage of home dialysis vary so widely in different parts of the country, I think it is a particularly good question to ask.

I would also, as a general statement, urge the committee not to lose sight of this point of quality of care. I think quality of care is hard to pin down, but it is my feeling that it is very uneven around the country from unit to unit, even from region to region. I am not sure about that.

Mr. SCHOEN. The only thing that I would suggest perhaps in another area of the study is how the ESRD program can enforce the very regulations that it has on the books? I have mentioned that I have tried to find someone or some entity to take responsibility for that. To this day, I do not know what the remedy would be if, for example, a unit is found violating a particular regulation. And to the extent that patients are captives of these dialysis units, they should have at least some reassurance that someone is watching over those units to make sure they are being run in the most efficient and the most appropriate way to maintaining not only a quality of care but the lives of the patients.

And, as I say, I have not been able to determine that. And I know a number of reporters have tried and they have been unable to determine that. And perhaps you can determine it.

Senator BAUCUS. Thank you very much.

Mr. BAUER. I would like to make a point. We are six patients here today. I don't know how many patients you have had before you in the past, but I would suspect not a tremendous amount of patients.

We four to the right of the panel as you look at us are members of the Patient Advisory Committee of the local network. We are a small voice in that network. The network is, in general I would say, dominated by medical professional people.

The patient, it seems to me, is the bottom line in the whole game that we are talking about, and yet not too many places do we find an opportunity to have an input. We are here today. If the Department of Health and Human Services had somebody in charge, as Dick Rettig said, that we could go to to articulate our particular concerns, that would be helpful. If the committee sought the advice of the patients more frequently perhaps, that would be helpful.

I think that all too frequently, I, as a patient, feel that there are not enough opportunities to express what our concerns are. And you have heard many of them articulated here today.

Senator BAUCUS. I appreciate that. I am sure that is true. That is partly why I asked the question. It gives me the opportunity to sound off.

Ms. LINDSAY. May I add one more thing? I think that a vital concern of the patients is patient education. Many times a person comes into the system and does not understand the alternatives and the different modalities. And this is exactly what he is up against.

Senator BAUCUS. But why is that?

Ms. LINDSAY. I think this is a function that the networks can take responsibility for.

Senator BAUCUS. Don't the physicians tell the patients what their options are?

Ms. LINDSAY. Not necessarily.

Senator BAUCUS. Thank you.

Mr. JONES. My name is Dan Jones, Daniel Jones. I was very glad to see that the patients' rights have been recognized. We need the patients to be participating in the analysis of the efficiency of programs, with how programs take place, how good they do, is encouraging. I just recommend that that attitude be continued and that patients become part of all of the development programs, the analysis of programs, and after analysis, reconstruction of such programs that are to become beneficial both to the patients and to all the costs of medicare to the U.S. Government.

Senator BAUCUS. Thank you.

We thank you all very much for your contributions.

Our next witness will be Dr. Christopher Blagg, director of the Northwest Kidney Center, Seattle, Wash.

Dr. Blagg, we thank you for your patience. And you have 5 minutes.

STATEMENT OF DR. CHRISTOPHER R. BLAGG, DIRECTOR OF THE NORTHWEST KIDNEY CENTER, SEATTLE, WASH.

Dr. BLAGG. Thank you, Mr. Chairman.

My written testimony addresses most of the points that were asked in the handout, and I would like in this testimony to talk about two areas in particular. One of these is home dialysis. There has been quite a discussion of this today. And I don't think I need to add anything to what the patient, Mr. Blackton, said about the advantages of home dialysis and why we feel that this, together with transplantation, is preferable for many patients.

Not all of them, however, and as Dr. Davis pointed out earlier, with the availability of funding for treatment of end-stage renal disease, the patient population has changed, and many patients now are not suitable for home dialysis.

However, one question asked that I think is worth looking at more closely is the issue of how we compare with other countries. Our rate is 14 percent. If you look at the data from the European Dialysis and Transplant Association, which incidentally has very good data, there are a number of European countries that have home dialysis rates of between 20 and 30 percent: Denmark, West Germany, Ireland, Sweden and Switzerland. Britain, as you know, has a higher rate, 64 percent. I will get back to that in a moment. Canada has 39 percent, and Australia and New Zealand have 47 and 48 percent, respectively.

So it is possible to get a high percentage of patients home. The problem is, as I think Dr. Rettig pointed out, that the percentage does not necessarily mean too much because the policies differ in different countries as to which patients get treated and whether there are any restrictions on access.

So perhaps a better way of looking at this is to compare the number of patients that are treated by home dialysis on a per million population basis. When you do that, the United States, based on figures from HCFA for the end of last year, is treating about 34 patients per million population by home dialysis.

Now the United Kingdom in fact is only treating 44 per million by home dialysis, Switzerland and Australia, 41; Canada, 47 patients per million population.

You might think from this perhaps, that if we could get between 40 and 50 patients per million home that would be a reasonable figure to aim at for the United States. But, as has also been pointed out, there is a lot of variation in the United States itself. In Washington State, the figure at this time is around 88 patients per million population on home dialysis. And, in Indiana, if my calculations from the network data are correct, this is around 83 patients per million. So there is certainly considerable room for improvement nationally.

Now this afternoon we have also heard mentioned 20 percent at home as a reasonable figure. I think perhaps 25 percent might be even more reasonable, but even if we only went to 20 percent, this means increasing the rate to about 49 per million. Somebody else asked what that would cost? At least, with my pocket calculator, I estimate this would save us something like $20 million a year.

So I think there is a lot to be said for an approach in terms of legislation and policy that would further encourage home dialysis.

This brings me to a brief comment about the organization and administration of the ESRD program. I believed in 1978 that we had stimulated Congress with regard to the encouragement of home dialysis and transplantation. A law was passed which was designed to improve these modalities, and yet it took some two and a half years after the provision related to changes in home dialysis reimbursement was supposed to have been implemented before instructions were published to make that process available. I feel it is essential that the ESRD program does remain as a discrete entity that you can get a hold of and shake if Congress is going to see that the things recommended actually get done within a reasonable length of time so that you can assess the results.

The other topic that I would like to talk about briefly is the issue of data collection. And really what can one say about data collection in the United States? It has been a disaster.

If one goes to the International Society of Nephrology meetings where they have a session at which physicians discuss data from different countries, it is an embarrassment to be from the United States in comparison with other countries. And I am not sure that the networks can collect data much better, though they certainly appear to be doing better than HCFA.

The data is there. The initial history form and the billing forms which are required to be paid for the services should provide access to the necessary data.

One suggestion that we have also heard mentioned is the possibility of consolidating median intermediaries, perhaps on a regional basis. Maybe doing that and letting them handle data from the billing forms might help to solve the data problem.

But I would also point out that the European Dialysis and Transplant Association, on a voluntary basis, collects data from 32 countries, something like 65,000 patients, and over 1,200 facilities. It does this on a once-a-year basis, with a single data collection once a year. It does special studies, and produces data which is reliable, useful and timely.

Finally, I would just like to add that the ESRD program itself has been a success and has provided ready access to care for patients. But, I do believe, as Dick Rettig pointed out, that the success of the program is related more to those who have provided the services than to the workings of the Federal bureaucracy and the implementation of Federal policy to this time.

It is important as you look at this program, as you look at what you are going to do with this in the future, that you do take measures to insure that home dialysis and transplantation are readily available to patients in all parts of this country.

Thank you, sir.

Senator **Durenberger**. Thank you very much for your testimony.

Let me start by asking you why we spend so much time discussing data and data collection?

Dr. **Blagg**. Well, people want to know how many patients there are, where they are being treated, and also what the results of that treatment are. I think that Dick Rettig's quote from the New England Journal typifies the problem.

We know how many transplants were done in this country last year. We do not know what the results of those transplants were. We do not know how many patients there are in the United States who got transplants that have survived longer than 3 years because these patients are no longer Medicare entitled.

We do not know nationwide how survival relates to age, how survival relates to different diagnoses. We do not know, as mentioned earlier by Dr. Davis, what is the rehabilitation rate. Somebody asked why this study is going to take 2 years. This is because the data collection is going to take until sometime in 1982, and then this has all got to be analyzed.

There are a lot of questions like these for which, 8 years into this program, we do not have the answers.

Senator **Durenberger**. In other words, what we are primarily looking for is medical data, which gives us the confidence to take another step in the process of assisting persons with end-stage renal disease.

Dr. **Blagg**. But very basic medical data. You do not need to have a great deal of it. Research studies should be done separately. But we do have good data. For example, it would be interesting to know how different transplant units compare in their results.

The question comes up, and has been argued back and forth, in fact once before this committee, is home dialysis less safe than in center dialysis? And so on. There are a whole number of questions that can be asked.

Senator **Durenberger**. Why are the States of Washington and Indiana better than anybody else? One possible conclusion is that you talk to each other and share information. Is that an appropriate conclusion?

Dr. **Blagg**. No. I think there are a number of factors. One obviously is that we are both single States that had good programs supporting end stage renal disease patients prior to the Federal Government becoming involved.

When money was short, home dialysis was used because this was the way to treat the most patients. So we had good home dialysis programs. Both States have one major university with a medical school, and most of the physicians within the State come out of that same training program and have been exposed to a successful home dialysis program.

One result of the end stage renal disease program was an explosive increase in the number of facilities, which were obviously needed to provide care for patients. We have also trained a lot of nephrologists in the last 8 to 10 years, some of whom have never seen home dialysis. And if you have not seen it and don't know successful home dialysis patients you have problems because the approach to home dialysis is patients, different the way physicians usually think. It is a complex process, but even so a patient can do it himself, safely, in the home. There are a whole number of reasons. I will also add, as we have been discussing deregulation, that in the State of Washington, where our health systems agencies are relatively good as compared with many areas that I hear about, we have always had a planning process with regard to dialysis. We have expanded dialysis facilities in our State at a slow rate. You have a dilemma with deregulation in that if you make dialysis stations too freely available, which means that any patient can get care readily, you are also going to adversely impact home dialysis and transplantation unless you take other measures. I think you are always going to have to have some sort of control in this program, but I am not quite sure how best do this.

Senator DURENBERGER. Your first response to my question about Washington and Indiana is that they had preexisting programs. Furthermore, when there were tighter cost constraints, the States had an incentive to develop cost-effective alteratives. If we develop the appropriate incentives shouldn't the system respond more favorably with alteratives?

Dr. BLAGG. Possibly so. But I think you also have to realize that, as you know, we have one big city in Washington State, Seattle.

Senator DURENBERGER. Where is Spokane?

Dr. BLAGG. And if you go to Baltimore or Washington or New York you have got a much more complex situation with many more providers. It is a very different political and medical situation.

Senator DURENBERGER. I have other questions, Doctor, but I really hesitate to keep you. And if I might propose those to you in writing I would like to do that.

Dr. BLAGG. I would be very happy to.

[The prepared statement of Dr. Blagg and his responses to Senator Durenberger's questions follow:]

STATEMENT OF CHRISTOPHER R. BLAGG, M.D.

Mr. Chairman, I am Dr. Christopher R. Blagg, Director of the Northwest Kidney Center in Seattle, professor of medicine at the University of Washington, Seattle, and past chairman of End-Stage Renal Disease Network Coordinating Council #2. I am testifying on behalf of the Northwest Kidney Center, and also on behalf of Dr. Belding H. Scribner, professor of medicine at the University of Washington, Seattle. Dr. Scribner devised the shunt which first made possible long-term hemodialysis treatment for end-stage renal disease (ESRD) and, with his coworkers at the University of Washington, has been responsible for development of much of the equipment and techniques used for hemodialysis and peritoneal dialysis. In addition, in conjunction with the medical and hospital community in Seattle, he was responsible for development of the Northwest Kidney Center as the first nonprofit, out-of-hospital, regional, outpatient dialysis facility in 1962. As a result of Dr. Scribner's leadership, the state of Washington has had a coordinated program for treatment of end-stage renal disease for many years. This has emphasized home dialysis and transplantation, has maintained one of the highest rates of home dialysis in the country, and is cost-effective as shown by the fact that the cost to Medicare for ESRD beneficiaries in the state of Washington in 1979 was 82% of the national average (1).

We would like to thank the subcommittee for this opportunity to submit our comments on the operation and management of the ESRD program in light of our experience in the state of Washington. We would like to preface these comments by affirming our belief that home dialysis and transplantation are preferable forms of therapy for many patients, and that any review of the past, present, and future of the ESRD program must consider the effect on home dialysis and transplantation.

UTILIZATION AND ACCESS

Minimum Utilization Rates and Certificate of Need.

Existing minimum utilization rates (MURs) do not reflect current medical practice, but were developed some 7 years ago when the average duration of a dialysis was longer than is now the case. Minimum utilization for unconditional approval of a dialysis facility presently is 80% utilization based on 2 shifts daily, 6 days a week, even though the average duration of a hemodialysis is appreciably less than the duration of a nursing shift, and nursing shifts now not uncommonly exceed 8 hours. Medicare reports that in June, 1981, there were 13,069 approved dialysis stations (2) and 44,812 patients on outpatient dialysis (3). This is approximately equivalent to a utilization rate of 86%, assuming a potential of only 2 patients per station per day. However, many facilities, even though not open round the clock, may dialyze 3 patients daily in a station, and in this case, the national utilization rate would be only 57%.

A major problem with MURs is that while these were established in order to certify a facility or center for approval by Medicare, the same MUR often has been used in planning as a criterion for deciding need for expansion or establishment of a new facility. A higher MUR as one criterion in the certificate of need process could encourage provision of evening and overnight dialysis which would be beneficial to working patients and could have cost-saving potential by encouraging greater use of home dialysis.

Our experience in the state of Washington has been that the certificate of need requirement, including consideration of utilization rates, does play a role in controlling program costs and may also impact quality of care as a result of planning criteria geared to controlled expansion in an orderly fashion and encouragement of home dialysis. In turn, this has contributed to control of the cost of the ESRD program in the state of Washington.

Provision of all modalities of care for the treatment of end-stage renal disease involves high-cost technology on a coordinated regional basis and is a service which we believe to be sufficiently complex to require regulation in order to contain costs, encourage home dialysis and transplantation, and encourage economies of scale and sharing of services between facilities. Generally, this regulation of ESRD services should be at the state level. If the certificate of need requirement were to be eliminated completely, with consequent uncontrolled increase in the number of dialysis stations, this would be likely to impact cost and quality of care, because experience has been that a rapid increase in the number of dialysis stations tends to be associated with a reduction in home dialysis and transplantation. Quality of care would be impacted as, with a surplus of competing centers and the probable future restriction of funding, there would likely be reduction of staffing levels and less flexible patient scheduling. Recently there has been shown to be an inverse relationship between the proportion of "for profit" dialysis units in a network area and the percentage of patients treated by home dialysis and transplantation (4). Thus, if as we believe, home dialysis and transplantation, as well as being more cost-effective, have other major advantages over outpatient dialysis for many patients, deregulation with its likely adverse impact on these treatments could have a deleterious effect on quality of care and result in an increase in cost to the program.

One major problem with deregulation and putting choice of therapy for a complex chronic disease with several possible treatment options solely in the hands of the consumer is that most patients cannot initially be regarded as informed consumers. The form of treatment a patient selects is influenced significantly during the first months of treatment, when he or she is sick, frightened and confused, by both the patient's physician and the facility staff. Deregulation would not be likely to improve the patient's ability to make a choice of therapy.

Patient Access and Patient Choice.

Patient access to facility and physician of their choice may be restricted by the policy of some dialysis units of restricting physician access. However, we believe that this is not an issue which should be regulated federally, and that it is the right of a facility to set its own standards regarding physicians who may practice therein. This concept is supported by much case law with regard to establishment of hospital privileges for physicians. Nevertheless, we would generally encourage facilities voluntarily to permit any qualified nephrologist to treat his or her patient.

With regard to barriers restricting access to home dialysis and transplantation, the fact that a preponderence of "for profit" units in a given area may reduce access to both these forms of treatment has been alluded to above (4). The problems for home dialysis in the ESRD program have been addressed in detail in a recent document developed by a number of professionals and patients concerned about the future of home dialysis in the United States. A copy is attached to this testimony. We believe strongly that there should be no restriction of access to home dialysis and transplantation and that home dialysis should be encouraged by making this treatment financially enticing to patients, physicians and facilities. While we realize that this hearing is not dealing with reimbursement, we would like to comment that we support the recent reimbursement change in the Budget because, at least in theory, the composite rate, if set at an appropriate level, should be an incentive for home dialysis. However, we are concerned as to how this can be implemented, as we do not believe that all 1,093 dialysis centers and facilities in the U.S. can or should establish their own home dialysis training and support programs. The requirements for successful home dialysis support are different to those needed for provision of outpatient dialysis, and a likely result of a reimbursement scheme forcing all facilities to develop their own home dialysis programs could be poor quality care. Consequently, the reimbursement mechanism should take into account how to give credit to facilities that refer patients elsewhere for training and support services. Patients should be free to choose their physician independent of their choice of treatment setting.

With regard to open market competition amongst providers of treatment, we believe that it is necessary to retain some planning control over development of new or expanded facilities, although this is best performed at the state level. The ESRD program is essentially a program for reimbursement of patient care, and is a federally sponsored market which is directly affected by government policy both with regard to constraints and incentives. As such, the program is not a classical free market.

Experience with Home Dialysis and Transplantation.

As of December, 1980, of the 52,364 patients on dialysis in the United States, 4,715 were being treated by home hemodialysis and 612 by home intermittent peritoneal dialysis (10.17% of the dialysis population), and 2,334 patients were being treated by continuous ambulatory peritoneal dialysis (4.46% of the total dialysis population). Thus 14.6% of the total dialysis population was treated by home dialysis (3). In comparison, as of December, 1979, several European countries had higher percentages of patients treated by home dialysis, including Denmark (23.2%), Federal Republic of Germany (20.8%), Ireland (33%), Sweden (22.3%), Switzerland (23%), and the United Kingdom (64.1%) (5). In Canada, as of December 31, 1980, 38.7% of all dialysis patients were treated by home dialysis (6), and as of October, 1979, this figure was 47% in Australia and 48% in New Zealand (7).

There are problems with interpretation of this data. If one assumes that the incidence of kidney disease is similar in various countries, it is obvious that the number of ESRD patients per million population receiving treatment differs from country to country for various reasons. For example, the European Dialysis and Transplant Association recently has reported a clear correlation between the number of patients treated in a country and the gross national product (8). In comparing the use of home dialysis between different countries, a better comparison would be based on the number of patients per million population being treated by home dialysis. In this regard, based on a United States population of 225 millions, the current rate of home dialysis (including CAPD) is 34 patients per million population. Based on data from the European Dialysis and Transplant Association as of December, 1980 (8), comparable figures for France were 39 patients per million population, and for the United Kingdom and Switzerland, 44 patients per million population. For Canada, the figure was 47 patients per million population as of December, 1980 (6), and for Australia and New Zealand as of October, 1979, this was 41 patients and 31 patients per million population respectively (7).

It should not be assumed from this that the limit for possible use of home dialysis lies between 40 and 50 patients per million population. In the state of Washington, as of December, 1980, the number of patients treated by home dialysis was 88 patients per million population, and in the Seattle area, this was 91 patients per million. Corresponding figures for Indiana and North Carolina were approximately 83 and 64 patients per million population. If 25% rather than 14.6% of all United States dialysis patients were being treated by home dialysis, a figure which we believe could be achieved within 2 to 3 years, this would be equivalent to 58.2 patients per million population.

In addition, in order to make information on home dialysis even more meaningful, it is necessary to know the number of patients living with a transplant so that one can compare the home dialysis rate to the total ESRD population. This is particularly appropriate because for many patients home dialysis and transplantation are the preferable forms of therapy. Such information is available through the European Dialysis and Transplant Association and other national registries, but is not available through the Medical Information System of the ESRD program which only has information on the number of transplants performed each year and has no reliable information yet on survival or mortality. In 1980, 4,697 transplants were performed in the United States. Assuming a population of 225 millions, this is a transplant rate of 20.9 per million population. This is roughly comparable to the rates in the European countries with the highest rates of transplantation, which are Finland (28 per million), Sweden (27 per million), Switzerland (25 per million), and the United Kingdom (18 per million) (8). Comparable figures for Canada for 1980 are 16.2 transplants per million population (6), and for both Australia and New Zealand in 1979, 21.9 transplants per million population (7). Thus, while all are aware that an appreciable number of U.S. patients are awaiting transplant, and while concern is frequently expressed about the relative lack of availability of suitable kidneys for transplant, nevertheless, at this time transplantation in the U.S. appears to compare favorably with that in other countries. Of course, this is not to say that this situation could not be improved upon.

PROGRAM MANAGEMENT

Reorganization.

The history of the several reorganizations already undergone by the ESRD program, and the impact of these, have been described in detail by Rettig (9), whose scholarly report to HCFA should be read by all interested in the ESRD program. It is our belief that the several reorganizations, the internecine struggles for power, the lack of continuity of senior staff with experience, and the frequent delays in obtaining policy decisions have all adversely affected the program. We feel that the ESRD program is sufficiently unique, complex, and of such potential significance for future health care policies that it should be separately identifiable and should have policy and reimbursement decisions, both of which, of course, require a strong data capability. We also urge that there be responsibility for this program at a high level in HCFA, with ready access to both the Administrator and to the Secretary. We believe that the impending disbandment of the Office of End-Stage Renal Disease during the current reorganization of HCFA is unfortunate, occurring as it did at a time when the OESRD staff appeared to be relatively stable, knowledgeable about the program, and showing capability of administering it, and also at a time when significant changes are occurring in federal reimbursement. It is in the interests of all of us, Congress, providers, and patients, that this staff remain stable, accessible, and responsive.

Performance of Intermediaries and Carriers.

The performance of intermediaries and carriers throughout the country has been extremely varied, and many facilities can recount examples of the inefficiency and lack of knowledge of a local intermediary with regard to the ESRD program. Responsibility for assessing intermediary and carrier performance should belong to HCFA, and better means should be found for addressing problems in this area. The effectiveness and efficiency of the ESRD operations of intermediaries and carriers probably could be improved by consolidation, although rather than one "national" intermediary and carrier, consideration should be given to one for each HEW Region. This could be a suitable area for encouraging competition between intermediaries and carriers for the privilege of handling this program. Consolidation would permit development of a cadre of experienced staff directing their efforts primarily to the ESRD program, would permit easier and clearer performance assessment, and could also provide a means of helping HCFA with data collection.

Program Integrity.

We are unaware ourselves of significant examples of fraud and abuse in the ESRD program. Certainly if these occur, they should be dealt with. However, we must express concern that because fraud and abuse are issues which receive a great deal of publicity, there is danger of overexpenditure of effort to expose problems which may not be significant. Obviously, at least up to now, there have been legitimate ways to be extremely well reimbursed, both as a physician and as a facility, under the ESRD program.

Networks.

To our mind, the major accomplishment of networks has been to provide a meeting place which brings together physicians and patients with other professionals involved in the care of ESRD patients. We have always believed that issues of planning and of quality of care could equally well have been addressed by appropriately constituted subcommittees of local Health Systems Agencies and Professional Standards Review Organizations. Network effectiveness has varied in different regions, and it is our impression that those networks which were based on preexisting geographic referral patterns, or which were restricted to a single state, have in general performed better than those networks which were mandated by HCFA without regard to preexisting referral patterns. However, network policies (and their results) often tend to reflect the makeup of the facilities in the network so that there may be very different treatment patterns in various areas of the country (4).

While individual quality of care studies may have been of value, we do not know of any evidence that networks have had significant impact generally on the quality of patient care. With regard to treatment setting and modality, there has been a slight increase in both home dialysis and transplantation over the last 3 years. However, there is nothing to show that this is in any way related to the networks, and the explosive increase in the use of continuous ambulatory peritoneal dialysis over the last 2 to 3 years almost certainly is the major factor contributing to the increase in the use of home dialysis. One could hope that the issue of treatment setting could be impacted by networks if their recommendations with regard to expansion or establishment of new facilities were based on an applicant's past history with regard to referral for home dialysis or transplantation. However, if networks are eliminated, this could still be part of a local planning process. As Rettig has commented, the present network budget of approximately $6 million, or more than $100 per patient each year, is difficult to justify by the results of network activities to date.

In the last year and a half, networks have become involved in collecting and transmitting much of the ESRD data, presumably as a result of the failure of HCFA itself to run an effective Medical Information System. While national data collection is essential, we are not convinced that 32 networks developing and collecting data separately is either an efficient or cost-effective way of doing this. There are alternative means of data collection which should be explored.

With regard to the need for networks to ensure quality of care, we believe this could be better addressed by local medical audit. While some networks have undoubtedly had an impact on facility planning, such planning could equally well continue at the local level through the state. Overall, we believe that network operations could be eliminated without detriment to the program and using other means of performing network functions.

QUALITY OF CARE

Facility Certification.

Facility certification and an on-site survey are of value when a new facility is to be opened in order to assure that health and safety considerations are met. Nevertheless, there is no need for a regular annual survey. Rather, providing an initial survey is satisfactory, this could be repeated on a 2- or 3-year basis, or prior to consideration of a request for expansion, or on receipt of a complaint with regard to a facility. Generally, the survey is a paperwork exercise which cannot assure that policies and procedures are being implemented. However, the possibility of audit on a random basis to ensure that record keeping and health and safety standards are being maintained might be considered and would be less costly to the program.

Quality of Care.

Monitoring of quality of care has, and continues to be, a problem for the ESRD program. The first requirement is adequate data from facilities, and this requires an effective Medical Information System. Probably the most effective monitoring of quality of care would be achieved by medical audit of the facility. Consideration should be given to the concept of a site visit by a nephrologist, perhaps in conjunction with a facility certification survey. Alternatively, medical audit could be contracted out to such a body as the Joint Committee on Accreditation of Hospitals. Prior to such a survey, the facility could be asked to provide specific medical information bearing on treatment, and of course it should be possible (in theory) to obtain information from the Medical Information System on patient numbers, demographics, treatment modalities, survival, hospitalization rate, reasons for hospitalization, and causes of death.

Staff Qualifications.

Staff qualifications and training and levels of staffing are issues which should be individualized to facilities and related to the treated patient population. This question has been studied by HCFA in the past. We believe strongly that it is the responsibility of the facility to provide appropriate staff and training, and that it is inappropriate for HCFA to regulate specific staff/patient ratios for dialysis or transplant facilities.

PROGRAM DATA AND RESEARCH

Medical Information System.

The Medical Information System has not provided useful, accurate, or complete data. It is our opinion that reliable and complete reimbursement, cost, treatment modality, and patient characteristics data is not available in usable form at this time.

The need for an accurate data collection system for the ESRD program has been stressed many times by ourselves and others, but without significant improvement occurring. Basic demographic data on patients supposedly is recorded on the initial history form (SSA-2742), and in theory this, together with bills generated for services such as hospitalization and all types of dialysis and transplantation, should be sufficient to provide basic information as to what is happening to patients. However, HCFA appears to be incapable of using bills to provide this information even though all facilities presumably bill for their services relatively promptly and this would eliminate the need for extra data forms. Perhaps HCFA's difficulty with use of bills could relate to a recent press report of problems with the Social Security Administration's computers which apparently are cbsolete and functioning poorly.

If there were to be consolidation of intermediaries, data might be collected through intermediaries and Regional Offices. However, a possible better alternative is exemplified by the European Dialysis and Transplant Association. The Association gathers data voluntarily from 32 countries and 1,149 centers and, as of December, 1980, had 64,973 living patients on file (8). This data is collected by means of an annual survey. Not only is sufficient information gathered to provide good statistical data on treatments, facilities, and countries, but special studies are also performed each year on problems of interest. As a result, the European Dialysis and Transplant Association is able to provide very useful and significant information to participants ranging from individual facilities to national programs (5). The cost of this data collection is very significantly less than the cost of the abortive efforts at data collection up to this time in the United States. We recommend study of one of their reports to those interested in seeing how embarrassingly well data collection can be done elsewhere.

We would recommend that HCFA and the National Institutes of Health begin at once working together to reinstitute a National Dialysis and Transplant Registry, with consultation from professionals in this country and the European Dialysis and Transplant Association. Because of HCFA's track record with data collection, the possibility of a contract to an outside agency or even to the European Dialysis and Transplant Association itself should be considered. With the likely elimination of networks in the not-too-distant future, the urgency of developing a data system cannot be overstressed if a further embarrassing hiatus in nationwide information is to be avoided.

With regard to the problem of a facility which does not provide requested data, the simplest sanction would be to reduce payment to the facility until relevant data is obtained.

Clinical research data needs should be met by special studies sponsored through the National Institutes of Health. These could be handled by a National Registry in the same way that they are handled by the European Dialysis and Transplant Association.

Studies and Experiments.

The most likely studies to have an impact in reducing program costs are those related to reuse of dialyzers. While this is a controversial and emotional issue, a great deal of evidence has been accumulated that this is a perfectly safe procedure, used by as many as 20% of patients worldwide. In our program in Seattle, we have been reusing dialyzers for almost 15 years. Despite the wealth of experience with reuse, the Health Industry Manufacturers Association still appears to be actively opposed to the concept of reuse. However, we would urge assessment of the results of recent studies on dialyzer reuse and subsequent federal support for this procedure. We would also suggest the possibility that for home dialysis patients who reuse, the savings that result be used to provide a financial incentive for home dialysis.

Most of the studies related to end-stage renal disease are carried out through the National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases, and the budget with regard to chronic renal failure currently is somewhat in excess of $4 million. The bulk of this is approximately equally divided between transplantation-related research and research into the consequences of uremia and chronic renal disease, and only a relatively small proportion goes to research related directly to dialysis. Until a few years ago, the Artificial Kidney/Chronic Uremia Program of NIH provided contract support for dialysis-related research, but this program has been phased out recently as a result of the policy at NIH of encouraging the use of grants rather than the contract mechanism for supporting research. Nevertheless, much of the research in the dialysis-related field lends itself to contract studies. In light of this, and of the continuing need for HCFA and other government agencies to address issues related to end-stage renal disease and its technology, we urge consideration of a new contract program specifically to provide funding for research into dialysis and related areas of ESRD treatment. Such a program could be administered through NIH, which would issue requests for proposals for studies in suitable research areas, and would provide peer review. Funding for such a contract program would come from NIH and HCFA, and from other interested agencies such as FDA, CDC, NCHCT, and possibly from private industry. Such a program would encourage further much-needed technical research in dialysis, and would also enable NIH and the professional community to assist HCFA in answering the many technical-related questions still associated with the ESRD program.

FINAL COMMENT

The ESRD program has been a success in that it has provided ready access to treatment for all patients with end-stage renal disease in the United States. Nevertheless, as Rettig has pointed out, the success of this program is attributable more to the competence of those who have provided the services than to the workings of a sound federal policy. With the forthcoming changes in reimbursement policy, it is essential that the operation of the ESRD program be reviewed to ensure the availability of prompt and reliable information, to ensure sound policy making by an informed bureaucracy, and to reconsider the issues of how to provide for coordinated services by planning, how to maintain quality of care, and finally how best to address the issue of cost-containment without adversely affecting quality of care. Criticism of the program is easy. The challenge is to make the ESRD program work better in order to ensure that all patients get the care best suited to their needs in a cost-effective program.

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ATTACHMENT FOR THE RECORD.

PROBLEMS AND SOLUTIONS FOR HOME DIALYSIS IN THE 1980'S

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PROBLEMS AND SOLUTIONS FOR HOME DIALYSIS IN THE 1980'S

Home dialysis, including hemodialysis and both intermittent peritoneal dialysis (IPD) and continuous ambulatory peritoneal dialysis (CAPD), is a treatment option for patients with end-stage renal disease (ESRD) that has been shown conclusively to be technically feasible, psychologically rewarding, conducive to better patient rehabilitation, and financially less expensive than outpatient dialysis at a facility. The patient, with assistance of spouse, other family member, or paid helper, can be trained in the safe operation of currently available dialysis equipment. There is no evidence that with home dialysis the risk to the patient is greater or the incidence of complications differs from that for comparable patients treated by outpatient dialysis. In fact, home dialysis may be safer because of personal control of the treatment and the negligible risk of acquiring hepatitis. Psychologically home dialysis restores to the patient a sense of independence and control over renal failure and its treatment. As a result, and because of opportunity for flexible scheduling, the potential for patient rehabilitation is increased. Once home dialysis training has been completed and patients have had opportunity to dialyze at home, this method of treatment is preferred by the overwhelming majority of patients.

Implementation of Public Law 92-603 in 1973 resulted in a number of obstacles, financial and otherwise, to use of home dialysis, while at the same time financially encouraging use of outpatient dialysis. One result was a decline in home dialysis in the United States from approximately 40% of dialysis patients in 1973 to some 11% five years later. Many of these obstacles were addressed to varying degrees in Public Law 95-292, passed in 1978, which legislated changes in reimbursement for home dialysis (target rate reimbursement) and for outpatient dialysis (incentive reimbursement). It is now almost three years since that legislation passed, yet the target rate is only beginning to be implemented and the incentive rate is still only a proposed regulation. The last two years have seen a small increase in home dialysis, from 11 to 14% of the total patient population, although much of this increase probably relates to the rapid growth in use of CAPD. There is nothing to suggest that this increase relates to Public Law 95-292, and present information is that only a small number of existing home dialysis programs will elect target rate reimbursement.

This position paper has been developed by a group of concerned professionals and interested patients who are involved in home dialysis at different facilities throughout the United States. The intention is to delineate problems with support of home dialysis in the Medicare ESRD program and to propose some possible solutions. Despite the changing patient population of the last seven years, which has resulted in an increased number of elderly patients and those with complicating diseases, we believe that a significantly greater percentage of patients are capable of home dialysis than presently are being treated by this modality. This is particularly important at a time of increased concern about the cost of health care. However, we also emphasize that the financial advantages of home dialysis are only one issue, and that the greater opportunities provided by home dialysis for patient understanding, independence, and rehabilitation should make this the optimum choice of dialysis treatment whenever possible.

The potential for increased use of home dialysis has been illustrated recently by the choice of CAPD by almost a thousand patients nationwide in the last year. We believe that many of these patients saw CAPD as a means of escape from outpatient dialysis in programs where other forms of home dialysis were not readily available. Early estimates are that many of these patients may not remain on CAPD, and the long-term ability to sustain patients with CAPD is not yet known. This is in sharp contrast to experience with patients trained for home hemodialysis, as there are an appreciable number of such patients who have been dialyzing successfully at home for more than ten years.

ISSUES AND RECOMMENDATIONS

These issues and recommendations were developed by review and analysis of current problem areas. Unless specifically stated, comments apply to both hemodialysis and peritoneal dialysis and include CAPD where appropriate.

1. HOME DIALYSIS TRAINING:

   The major problems in the area of home dialysis training related to misinformation, accessibility, attitude of physician, staff and facility administration, overabundance of outpatient dialysis stations, and present facility reimbursement for training.

   a. Misinformation and accessibility: Many potential home dialysis patients enter and continue outpatient dialysis through lack of patient knowledge or as a result of physician, staff, and management bias against home dialysis.

      Home dialysis training may be unavailable at a facility or in its geographic vicinity, and/or professional prejudice may prevent referral of patients for training.

      All ESRD patients should have an understanding of all the various modalities of treatment and of the advantages and disadvantages of each as these pertain to them as individuals. In order to achieve this, simple standardized educational material should be available to all new patients, and each facility should have a means of providing patients with information regarding treatment alternatives available at that institution and those available elsewhere by arrangement. This must include clear information on opportunities for home dialysis and transplantation.

   b. Physician, staff, and facility administration attitudes: A major factor operating against home dialysis often is lack of a positive physician attitude to this modality of treatment. There are many possible reasons for this, including the financial advantages of outpatient dialysis and lack of experience with home dialysis and of its effectiveness and safety. We recommend that physician reimbursement disincentives should be eliminated (see below).

Another significant reason for opposition to home dialysis, at least in some cases, appears to relate to physician ownership or interest in ownership of facilities. Consideration should be given to controlling this potential conflict of interest.

Staff attitude usually reflects physician attitudes. The attitude of facility administration also represents ownership and its possible conflict of interest.

c. Availability of dialysis stations: An important step to encourage home dialysis would be some constraint on continuing expansion of capacity for outpatient dialysis. This must be restricted, and expansion and opening of new dialysis units should be related to meeting an appropriate local goal for the percentage of new patients being trained for home dialysis.

d. Facility reimbursement for home dialysis training: Facilities undertaking home dialysis training should be fully and promptly reimbursed for all costs involved in training patients, including the full educational costs of the program. Current reimbursement is related to the number of procedures rather than to the procedures as part of the educational program. It would be preferable that the cost of training be reimbursed at the 100% level. Reimbursement methodology should allow for individual facility variation in training program and scheduling.

2. CERTIFICATION OF HOME DIALYSIS TRAINING FACILITIES:

Contrary to recently proposed regulations, we oppose certification of facilities providing only training (for any modality of home dialysis) and of training facilities which provide only self-care dialysis in the facility unless such facilities are part of a program providng all modalities of dialysis in a nearby related facility. Self-care dialysis in a facility is not clearly defined, can be used as a means of avoiding the issue of home dialysis, and is better achieved as a result of financial constraints on reimbursement for outpatient dialysis. We believe that certification of training-only facilities will lead to further fragmentation of the ESRD program. Training should be carried out only in renal dialysis centers or facilities meeting minimum utilization rates for training in order to take advantage of economies of scale and development of expertise.

We recommend that home dialysis training facilities be certified on an annual basis and meet existing Medicare standards as either a renal dialysis facility or renal dialysis center. Training stations in certified facilities should be exempt from the usual minimal utilization rate, and annual certification should require a minimum of training activity necessary for maintenance of expertise. This should be at least 12 new patients trained per year for home dialysis or CAPD, 6 per year for intermittent peritoneal dialysis, or if a facility provides training for more than one modality of treatment, a cumulative total of at least 20 new patients trained for home dialysis per year. Exceptions to these rates should only be granted on a geographic basis. Facilities must maintain records of training activities including information on the number of patients starting training, the facility the patients came from, the number of patients completing training, their disposition, and the success rate of the training program.

We recommend that a survey be made of training stations and related resources currently available. We believe that there are a large number of "training stations" not being used for training at this time, and that it has been a common practice for facilities applying for expansion to include such stations in their applications with no intention of using them for training purposes. If a survey records this to be the case, such stations should be decertified.

We recommend that consideration be given to establishment of regional home dialysis training programs. Successful training requires suitable space, staff, and materials, and is best carried out in a program training a significant number of patients annually. Too many centers give lip service to training and yet do not train patients. A regional center can train patients effectively and speedily, return them to the care of their referring physician, and provide coordination of all necessary support services. Such a regional center would be more feasible if it were able to provide travel and subsistence support to the patient and partner during training (see below).

3. HOME DIALYSIS SUPPORT SERVICES:

Provision of high quality, readily available support services is essential for the patient dialyzing at home. Continuity of medical care through a local nephrologist must be maintained, but in addition, there must be continuity of nonphysician professional and other support in order to maintain the environment permitting patient independence to prosper over the years.

Supplies, equipment, and equipment maintenance services must be provided either directly by the training facility or the training facility should insure these are provided by arrangement, either through manufacturers or the referring dialysis facility or center.

If provided by arrangement, the training facility must take responsibility for insuring the quality of services provided. In addition, nonphysician professional support, including social worker, dietitian, home visiting nurse, etc., must be provided directly by the training facility or by arrangement.

4. HOME DIALYSIS AIDES:

The use of paid home dialysis aides for patients wishing to dialyze at home and who lack a family member available or willing to assist has proved extremely helpful to some home dialysis programs. We recommend that use of such aides remain an option available to a home dialysis training program if desired. We recommend that HCFA not set standards for such aides, but rather permit individual facilities to set their own criteria for patient eligibility for an aide, payment mechanisms, and training. We believe that as a general rule, aides should not be nurses or technicians, except where required by State regulations, but rather individuals hired by the patient and trained to the same level as a family member. A facility should have the option to maintain a cadre of aides available to go to patient's homes as and when needed, but this should not be mandatory.

With regard to reimbursement, it is not clear that the present option of target rate reimbursement will provide sufficient funds for reimbursement of aides. Below we recommend other options for payment of aides and home dialysis which should be considered.

5. REIMBURSEMENT:

Reimbursement remains the major factor affecting where patients dialyze. The method of reimbursement instituted in 1973 had a severe impact on home dialysis which has never been overcome. We believe that in addition to potential cost-containment, home dialysis is the preferable form of treatment for many patients, and as such not only should any disincentives be removed, but incentives should be provided.

a. Reimbursement for home dialysis training: We recommend that facilities certified for home dialysis training be reimbursed on a cost basis for home dialysis training and for training of family members and aides rather than on a per-dialysis basis. This enables reimbursement for training activities not directly related to the patient's own dialysis and which are essential for a quality training program. In addition, we recommend 100% reimbursement for home dialysis training as an incentive to the facility.

We recommend that consideration be given to providing reimbursement for training by staff from a certified home dialysis training facility when this training is performed in a patient's home.

This would apply only in special circumstances, including training of hepatitis B-positive patients at home in order to minimize the risk of contamination of the facility.

We also recommend that consideration be given to the possibility of a mobile training program--nurse and materials--which could be reimbursed for going to a small unit in a geographically remote area in order to train a patient.

b. Facility reimbursement for home dialysis support services: In order to make target rate reimbursement more effective, we recommend that a limit be set on home dialysis charges billed by a facility on a per-dialysis basis if the facility does not elect the target rate option. Some facilities and suppliers are charging an excessive mark-up on dialysis supplies, thus making their per-dialysis charge for home dialysis greater than for outpatient dialysis. We recommend that a limit be set at (say) 10% below the national average charge for outpatient dialysis for such reimbursement.

In order to provide an incentive for facilities to use target rate reimbursement, we recommend that the facility have the option of sharing with the patient any surplus derived from the target rate, and that this sharing should be an allowable expense to the facility in their Medicare cost report. Similarly, any payments to spouse or family member for home dialysis services also should be an allowable expense to the facility.

We believe that the target rate, or any rate set each year for home dialysis reimbursement, must not be dependent upon the previous year's average outpatient dialysis reimbursement rate, but must be adjusted by an inflation factor such as an index of the increase in medical and other costs.

We recommend that consideration be given to the development of totally new methods of dialysis reimbursement, and in particular, the use of a uniform or composite rate of facility reimbursement for all dialyses, whether these are performed as an outpatient or at home. We believe that setting such a uniform rate at a level close to or slightly below the proposed incentive rate could be adjusted so as to encourage further use of home dialysis because of the potential for generation of surplus or profit.

Alternatively, we recommend examination of the target rate level and whether 70% of the outpatient rate is appropriate. The possibility of a phased-in new target rate, starting at say 95% of the incentive rate and decreasing by 5% per year while cost data and experience is collected, should be considered.

c. Reimbursement and the patient: It is essential that reimbursement for home dialysis should be adequate, and preferably this should be sufficient to provide incentive for the patient to consider home dialysis.

We recommend that all home dialysis training facilities use the 100% reimbursement option for capital equipment costs, either through the training facility itself or a nonprofit entity. This is presently available as an option, but mandating this would result in benefit to the patient without detriment to the facility.

We recommend investigation of the possibility of legislating a tax deduction for provision of dialysis services in the home by a family member or aide as a possible means of providing support to pay for an aide and, more importantly, to pay for services provided by the patient and family member. The recent introduction of S-3264 to amend the Internal Revenue Code to permit such a deduction for medical services in the home for individuals over the age of 65 is an example of such legislation. However, because a significant number of dialysis patients are of low income, the possibility of a tax credit for such patients should be considered. The potential advantage of this approach is a reduction in the target rate with support to patient and family coming from general tax funds.

As commented above, a facility should have the option of sharing with the patient any surplus derived from the target rate and also should have the options of paying a family member for home dialysis and of providing a paid aide if desired.

Payment should also be provided for travel and subsistence for patient, family member, and/or aide during home dialysis training at a certified training facility where the distance involved is greater than (say) 50 miles.

d. Physician reimbursement: We believe that a significant incentive for home dialysis would be provided by making physician reimbursement under the alternate reimbursement method (ARM) identical whether a patient is treated at home or as an outpatient. This would be more equitable than the present arrangement. If this is not done, we recommend strongly that the individual nephrologist be permitted to elect the ARM for home dialysis patients while continuing to receive fee-for-service reimbursement for outpatient dialysis patients. This would merely require a change of regulation but would provide a financial incentive to physicians.

Conclusion:

Home dialysis remains a desirable treatment entity for many reasons, and yet currently this is not being used as extensively as would be appropriate. We believe that some or all of the recommendations described would assist in encouraging home dialysis. Although these proposals will increase the cost of home dialysis, we believe that in the long term, the overall costs of the ESRD program will be reduced as compared to the cost of a national program based on the use of outpatient dialysis. We also believe that as a result of greater use of home dialysis, patient care and rehabilitation will be improved and more patients will be able to return to work and contribute to the general tax base.

We will be delighted to elaborate further on any of the above comments or recommendations at any time. We feel strongly that home dialysis is a more efficient and desirable method of dialysis treatment for many more patients than is the case at this time, and we would like to see incentives from the Health Care Financing Administration to permit this modality of treatment to be implemented on a competitive basis with outpatient dialysis.

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DEVELOPMENT OF A REGIONAL HOME HEMODIALYSIS TRAINING PROGRAM

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THE DEVELOPMENT OF A REGIONAL HOME HEMODIALYSIS TRAINING PROGRAM

A. The Problem - As everyone knows, home hemodialysis is lagging badly in the United States. Furthermore, past experience indicates that among the 50,000 plus patients already accustomed to in-center care, there is enormous resistance to changing to home care, and there is apathy and even active opposition from certain quarters to increasing the utilization of home dialysis.

B. Reasons for Failure - Clearly the present approach to the problem of increasing home dialysis is not working. Furthermore, recent HCFA data appear to indicate that among those centers attempting training for home care, the failure rate is very high.

At the same time, data from centers which are successful with home dialysis reveal that very specialized services and organization are required to operate a successful home hemodialysis program. Few centers presently have the capability or the resources to provide these essential services. Finally, it is quite apparent that unless a home dialysis program has a minimum number of patients to care for, it cannot maintain either the expertise or the necessary supporting services to do a quality job in a field where quality is a necessary prerequisite to success.

C. A Regional Home Dialysis Program - One, and possibly the only solution to this problem of increasing home hemodialysis in the United States is to develop a network of hemodialysis centers which are designated as regional home dialysis training and support centers.

D. Characterization of a Regional Home Hemodialysis Training and Support Center - A regional center will have the following capabilities:

1. A multidisciplinary planning process to assure consideration of necessary information to allow for optimal patient rehabilitation on home dialysis.

2. Medical and nursing direction/support to assure qualified staff, pertinent program content, and appropriate dialysis equipment.

3. A program designed to assist patients to identify the primary learner, be this patient, family member, or nonfamily member.

4. Training staff comprised of nurses and possibly technicians.

5. a. A training program which is educationally sound and individualized to patient needs, including assessment of learning capabilities, stated objectives, training schedule, lesson plans, and evaluation process.

   b. This training program should not only be available for initial training but should have capability for retraining as well; i.e., new helpers, new equipment, change of access, or refresher training.

6. Administrative support for processing of training materials, necessary record keeping, and financial coordination.

7. Supportive working relationship with the patient's physician to provide appropriate medical input to the patient's plan of care and to ease the transition between dialysis environments.

8. Dietitian support to assess nutritional needs to assure proper understanding of diet regimen as well as to provide support or assist with problem areas during training or as the patient is at home.

9. Social work support to facilitate patient logistics surrounding training; i.e., transportation, lodging, care of other family members, etc.; to provide emotional support throughout the course of training; to assist the patient in adjustment to home dialysis and maximum rehabilitation, including vocational; and to be available to patients on home dialysis for psychosocial and/or financial concerns.

10. Counselors (may be done by social workers) to assist patients with financial plans/problems/concerns surrounding home training and home dialysis.

11. Technical support to assess and advise regarding home alterations, to assist with equipment and water treatment installation, and to provide expertise for equipment repair and follow-up as needed.

12. a. A review mechanism that at least monitors, assesses equipment (dialysis and water treatment) safety and function in the home environment, assures patient possession of current appropriate procedures, and provides feedback on dialysis-related problems.

    b. A program for visitation which permits assessment of the patient in the home environment, assessment of the technical and procedural aspects of dialysis as performed by the patient, and provides follow-up or referral for problem areas as necessary.

13. A system for provision of dialysis supplies to the home that minimizes patient involvement to the degree possible.

14. Facility dialysis to allow backup for medical, technical, or social reasons, including respite from home dialysis.

15. Resources to allow the patient to maximize benefits of home dialysis and rehabilitation including: (a) facilitation of arrangements for vacation dialysis be this in a center using portable equipment or assisting patients to arrange to move their own equipment; and (b) a communication network to keep home patients apprised of changes in routines, procedures, equipment/supply items, and common problems.

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QUESTIONS SUBMITTED BY SENATOR DURENBERGER AND ANSWERS BY DR. BLAGG

1. Your Network has more than 40% of its patients on home dialysis, yet other Networks have as little as 5% on home dialysis. Why does the use of home dialysis vary so much; is reimbursement or professional judgment the reason?

   There are several reasons for the variation in use of home dialysis. This does in part relate to professional judgment and experience, but reimbursement probably is the major reason. Home dialysis continues to be practiced on a significant scale especially in Washington, Indiana, and North Carolina, and also in some other smaller localities. Each of these states has one (or in the case of North Carolina, three closely cooperating) medical school(s), and in each state the practice of nephrology has been closely related to the university program which has provided the majority of the nephrologists in private practice. During training, these nephrologists have been exposed to a successful home dialysis program and its advantages.

   Nationwide, generous reimbursement for outpatient dialysis rather than home dialysis and the ready availability of outpatient dialysis stations have played a major role in limiting home dialysis. The last 8 years has seen both a rapid proliferation of dialysis units in response to availability of generous financial support for outpatient dialysis, and the training of large numbers of young nephrologists who have not been exposed to home dialysis prior to going into practice. Many of these nephrologists were trained in programs which have used outpatient dialysis as a significant source of support for their training programs. Home dialysis has been well supported financially and requires more complex effort on the part of the dialysis facility.

2. You have preferred to see quality of care insured by local medical audits rather than Networks. Who would perform these audits and what do you mean by local?

   I believe this question is based on a misunderstanding of the intent of my statement. I have suggested that in addition to the need for adequate data, monitoring could best be achieved by a site visit to the facility by a nephrologist, perhaps in conjunction with the facility certification and survey. I have also suggested that such audits could be contracted out to a body such as the Joint Commission on Accreditation of Hospitals. I believe the nephrologist should not be from the local community. What I meant by local was that the audit should involve on-the-spot assessment in the facility rather than a more general medical care evaluation study by the Network.

3. What alternative means of data collection do you feel will be effective if Networks are eliminated? What data is needed?

As I have testified, I believe that data collection might be carried out either through the intermediaries, assuming these are regionalized, associated with the Regional Offices, or alternatively by contracting the whole medical data collection system to an outside organization.

With regard to the data needed, from a management point of view this is relatively simple and should include demographic data about the patients and their origin, race, age, sex, diagnosis, information on the modalities of treatment and where this is usually carried out, transplantation, failure of transplant, hospitalizations, and death. Much of this data could be collected from the billing forms supplemented by an annual survey. Other data could be collected by special studies.

4. You state that each facility should be left to determine its own staff and training needs, but how do we know whether the resulting costs are legitimate?

I assume that in the future the reimbursement rate will be set by the Health Care Financing Administration and that facilities will be free to operate within this reimbursement rate. If a facility has to request an exception to the reimbursement rate because they have, for example, more RN's than is usual, then the facility should have to demonstrate that this is necessary, based on their patient population.

5. What has been the experience, in both your facility and the Network, with the success of patient rehabilitation?

   There is no good data available on this either directly from our facility or from the Network at this time. However, many of our patients, particularly those on home dialysis, remain at work, and we believe our rehabilitation rate is significantly better than that reported by Gutman et al. in the New England Journal of Medicine earlier this year. Our facility was one of those studied last year during the service delivery assessment that the Department of Health and Human Services conducted on the End-Stage Renal Disease Program. This group interviewed a number of our patients selected at random and informed me that they were impressed by our staff's emphasis on rehabilitation and by the patients that they saw.

6. Are minimum utilization rates at all necessary to assure that some minimal level of staff expertise is maintained? Is that a problem with hemodialysis like it might be with transplantation?

   Yes, I do believe that minimum utilization rates play a role in insuring a minimum level of staff expertise. Of course, this is most difficult to document, just as it has been difficult to demonstrate this for transplantation, because of the many factors affecting mortality and morbidity. Also, as I have testified, I believe that minimum utilization rates and some limitation on the number of stations is important if home dialysis and transplantation are to be encouraged.

7. Whether or not a facility sets its own standards regarding which physicians may practice, do you feel that the decision to grant a physician privileges should be made on any other grounds than his qualifications? Should he be denied access to a facility simply because the ownership doesn't want anyone else to treat patients in the facility?

   My personal belief is that the decision to grant a physician privileges should be based solely on his or her qualifications and that it is inappropriate for the federal government to interfere in this issue. Nevertheless, I also believe that facilities should be urged to provide open access to qualified nephrologists in order to minimize the pressure for duplication of facilities. I appreciate the advantage to a facility in dealing with only a small group of physicians but believe that this may be outweighed by the advantage of size and lack of duplication if all local nephrologists have access to one facility.

8. Is reuse a realistic procedure for home patients or is it more adapted to facility care?

Reuse is perfectly adaptable for home dialysis patients. Our patients have been doing this for almost 15 years as part of our cost-containment efforts. This has allowed us to use state and donated funds for other purposes such as dialysis aides. The process requires some simplification for home reuse, and patients need careful training. Nevertheless I know of no serious problems which have resulted because of reuse in our home dialysis population, and this represents more than 300 patient years of experience.

9. What cost-containment measures do you feel are possible in light of the growing cost of the program?

The most obvious are to increase use of home dialysis and transplantation and to encourage dialyzer reuse. It is my belief that these can be best obtained by financial incentives for home dialysis and transplantation and disincentives to outpatient dialysis, which however must take into account the inability of some patients to do home dialysis for medical and other reasons and the lack of suitability of many patients for transplantation. Much of this is discussed in the attachment to my testimony. Reuse also is important.

10. Are you aware of any overuse of dialysis, particularly in the inpatient setting? Is that an issue that needs exploration?

No, I am not personally aware of any overuse of dialysis in the inpatient setting, although from time to time I have heard rumors of this. I suggest that this cannot be very widespread. Perhaps a greater concern would be to review the costs and charges for dialysis in the inpatient setting, both from the point of view of cost of the procedure itself and the physician fee. It has been suggested that in some places the charge for inpatient dialysis may be very high in comparison with cost, and this may be a significant cost to the ESRD program.

11. You suggest that home training be done at regional centers--how do you provide incentives for such training and is it a reasonable option to training at every facility? How do you make sure that the referring facility gets credit for the patient?

Yes, I do believe that home dialysis training should be done at regional centers. I am attaching to this response a brief position paper that we put together on this subject. We believe this to be a much better option than expecting that every facility will develop a training program. The latter we feel could well result in poor home dialysis training and support for many patients. As far as incentives go, we suggest examination of the possibility of some financial incentive to facilities which refer patients to a regional center, as well as the possibility of funding support to assist in development of regional training centers and training of their staff where a number of facilities are prepared to cooperate to develop such a facility. The problem of how to insure that a referring facility gets credit for patients is one which I do not know how to solve, although this is an issue raised by the composite rate. A possible solution in a program such as ours would appear to be a sharing of reimbursement for the home dialysis patient between our facility, which provides training and all support other than dialysis, with the facility that provides backup dialysis to the patient. It is my hope that the Health Care Financing Administration will come up with an innovative solution for this question as part of their new regulations.

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Senator **DURENBERGER.** I will leave you at this point as I will have to go vote. Our next witness will be Dr. John Sadler.

Dr. **BLAGG.** Thank you, sir.

Senator **DURENBERGER.** Thank you very much for your testimony.

[Whereupon, at 4:10 p.m., the hearing was recessed.]

AFTER RECESS

Senator **DURENBERGER.** I thank you all.

Our next witness is Dr. John Sadler, Renal Physicians Association, Baltimore, Md. Dr. Sadler, we welcome you.

STATEMENT OF DR. JOHN SADLER, RENAL PHYSICIANS ASSOCIATION, BALTIMORE, MD., ACCOMPANIED BY DR. NORMAN DEANE, PRESIDENT OF THE RENAL PHYSICIANS ASSOCIATION

Dr. **SADLER.** Thank you, Senator Durenberger. With me is Dr. Norman Deane, who is the president of the Renal Physicians Association, who wishes to be here to represent the membership along with me.

You have our full testimony in writing, and I would simply like to provide emphasis to a few points in that in my verbal testimony.

First, with regard to the management of the program, I have to say that we differ completely with Dr. Davis' interest in integrated management since we believe that integrated management would remove any likelihood of accountability and of visibility and of identifiability of this program. And as characterized by Dick Rettig, it will require it or the attention required may disrupt all of HCFA's functioning.

I think we find that the same thing has been happening in the intermediaries for years, where the ESRD program has been criticized on the basis of the dollars it consumes, but then has been denigrated because it is only a few patients. And I can see the same thing happening on a larger scale across HCFA were that management system chosen.

There is considerable question about the intermediaries' function because they vary so widely across the country. You have raised the issue of competition in this program. And I would like to suggest to you a form of competition that might be productive. If the providers were each able to choose the intermediary that served him best, those successful intermediaries might then have a large enough staff to deal appropriately with data collection needs, with the handling of program policy and procedures in an effective way, and the larger fraction of the business they receive would reward them for carrying out those functions. In like fashion, those intermediaries who did not do that would be appropriately rewarded also.

We do not believe that free market competition among facilities is a practical option with the knowledge we have presently, because there is a necessity for integration, both vertically and horizontally, among facilities. The requirement for skilled people and for all levels of care for all patients really requires some sort of structure. We don't want you to construe this as a commendation of the health planning process, but we do think that some structure is required.

In terms of program management, it would be improper for me to leave without throwing a few rocks at the Bureau of Program Policy, which has clung to those principles with which they were familiar and were rigid, not innovative and not particularly helpful to the ESRD program. So we find that, in general, their function is characterized by delay, rigidity and resistance.

The Office of End Stage Renal Disease, which has contact with patients and providers, does not have policy authority and is often frustrated by the lack of appropriate flexibility in policy management. We believe that should be noted unequivocally.

We believe, further, that the program is neither controlled nor documented, and it may be that the lack of documentation is why it is not controlled.

We talk of quality of care, and you should know that quality of care, review of care to understand quality is not cheap. Somebody has to do it, and it is going to cost something. And when we talk about cost saving, that may be an expensive luxury with which we have to dispense.

If you wish to review the program, the most efficient way is to review the data in the program on where the patients are. The service data on the bill that is submitted contains patient tracking information that will tell you where they are, what kind of treatment they receive, what morbidity they experienced, and through the absence of morbidity, a high quality, well restored patient. That is available. It could have been obtained by the intermediaries, were they ordered to do so and were that data handling a part of their assessment. But it has not been.

Some networks presently obtain that data, but it is not a consistent practice, and so nationwide data is not available. But data collection provides an option for saving in review.

We believe that cost savings are available through that mechanism, and possibly through reuse, which is being studied, through advances in transplantation, and, finally, through research which will reduce the need.

We do not believe that there are changes in the program as it exists presently which will give us sudden and marvelous savings.

I think I need to say one more thing about competition. Physicians and other health professionals do not compete for quality of care because of the pay they get for it. They are basically competitive people, and we compete among ourselves in many arenas, mostly with professional standards and with production of information and high quality patient populations that are not directly related to the income we receive for it. And a recognition of that kind of professional competition should give some comfort to those who wonder how to pay us in a way to make us do a good job.

Thank you.

Senator DURENBERGER. Thank you very much.

On the whole subject of competition, would you describe for me the incentives in the present reimbursement system for physicians to improve the quality of care while reducing the cost?

Dr. SADLER. The incentives right now for quality of care, as I say, are principally professional and personal incentives. The program itself does not provide strong incentives, except that if one is not only doing a good job but keeping a lot of paper to indicate it, your annual survey is less trouble. If you don't keep the paper, the quality of your work is of no importance.

The fiscal incentives for doing a good job, to my way of thinking, is that I do not have enough physicians in my group to take care of the number of patients we see unless a significant number of them undertake transplantation and home dialysis. For the amount of effort that it requires of us to take care of a stabilized, thoughtful home dialysis patient, we are better paid than we are for the amount of effort it takes for the patient who is unable to get out of the facility.

I would again point out that the recognition that patients in a center are not likely to go home, but that new patients will go home is an important perception. Once a patient has overcome a life threatening illness, when he really felt very bad and knew that he might die, it is very hard for him to let go of whatever he is using to avoid that. And to tell him that something else is better really requires that he not become so devoted to what he is doing presently, before he undertakes the change.

Senator DURENBERGER. Could you please comment on open staffing for qualified physicians.

Dr. SADLER. The Renal Physicians Association has said that open staffing is an answer for which there is no question. We don't see it as a problem, nationwide. There may be exceptional circumstances in which a specific consideration would be required, but we believe that cohesive leadership, standard operating procedures, and teamwork are the essence of a high quality facility. And it is possible to do that with an open staff or with a closed staff, but there definitely has to be a structure, leadership, and a cohesive sense of direction. We don't think that open staffing is a necessary boon in that environment nor that it is really a significant national problem.

Senator DURENBERGER. What is the impediment to greater transplantation?

Dr. SADLER. I believe that a lot of it is what I have just expressed, that for patients who become securely established in incenter dialysis after being frighteningly ill, if they become too stable, secure and dependent in that situation, have a hard time emotionally letting go and undertaking transplant. And, of course, the patients they see from transplantation are those whose transplant failed and came back to dialysis.

The patient who does well after transplant continues to go on and use his life, and does not very often come back to the unit to help it convince the others to go forward.

I believe that we are making significant scientific and medical progress in transplantation, and that with that progress and increased success, the visibility of that success and the encouragement of patients and of other health professionals to participate in the process will be increased and that will help us.

Senator DURENBERGER. What, in your opinion, accounts for the wide variance in the incidence of home dialysis?

Dr. SADLER. Some of it depends on the population of patients, the community, the political environment. A great deal depends on the physician's attitude and knowledge about home dialysis. Those of us who have done a good bit of it find it very rewarding. But if you have never done it, you may see it as threatening, that your patient will be a long way from you should something go wrong, or that you have to have a staff available to provide backup services and things are a little less consistent.

I think that health professionals, like patients, can become dependent on a structured situation with which they are very comfortable.

Senator **Durenberger**. What about the difference in patients being treated in hospitals versus free-standing facilities? Is there anything that indicates one kind of patient will go to one rather than the other? What has your experience been?

Dr. **Sadler**. That is a complex question that doesn't have a single answer. In a small community, for instance, dialysis is usually only provided in a hospital because all levels of care have to be provided in that hospital. The patient who is sick and needs dialysis has to be in a hospital. The patient who is stable and needs dialysis is usually not a member of a large enough community to justify the existence of a separate free-standing facility and the economies of scale don't exist.

In major metropolitan areas, however, it is possible to focus and to have a facility that is designed to do self-care and home dialysis training; a facility that is designed to provide stable maintenance dialysis in a facility with maximum efficiency; and a facility that is designed not to maintain anybody but just to provide backup care to those patients who have problems intercurrently or those patients who really are never able to be stabilized.

However, a hospital may own a lot of property that it doesn't really have to use. Sometimes we mistake hospital ownership for in-hospital location of a dialysis facility. That, I believe, has led to a lot of the confusion that exists in the assessment of where patients are dialyzed, what it costs, and what kind of facilities they are. There is a lot of variation in different communities regarding that.

Hospital ownership is not the issue. It is whether the patient is in a setting where the cost associated with the higher level of care is applied to a dialysis unit, which may not be necessary, or whether the hospital happens to own essentially a free-standing facility somewhere on its property; where it should be able to provide the same care with the same economy as a completely free-standing facility. But in every instance the patient should be able to go to the most pleasant, most efficient unit, but he has to have access to backup services and to transplantation which requires a hospital.

Senator **Durenberger**. Given a community in which a choice exists, are there some common characteristics such as age, sex, medical complications, or secondary diagnosis that indicate who will make the choice of a free-standing facility versus a hospital?

Dr. **Sadler**. I think that patients tend generally to be referred by a physician to a physician or by a community to the hospital that serves that community, and then to stay in the system of care in which they begin receiving care. I think that is a greater characteristic than the individual characteristics of the patient.

As you have seen earlier today, people who are ambitious and independent in their own right have a fair amount of latitude, move about a good bit, and develop quite a bit of sophistication about their care. That is irrespective of where they begin or what kind of care they are initially offered. But most patients who don't have that level of aggressiveness of understanding tend to just stay with whatever they begin with. I think that you can draw your own conclusions from that.

Senator **Durenberger**. One of the conclusions that I could draw from that is that patients become heavily dependent upon the physician that is involved in their treatment. I have heard a great deal today about the absence of good information and complaint systems.

Is there some blame to be laid on physicians for failure to provide the best alternatives?

Dr. **Sadler**. There is hardly any sin that some physician cannot be accurately accused of. But I would say that I think that the sense of having nowhere to complain, no redress of grievance may be more a perception than a fact. For instance, in my own city of Baltimore, if one of my patients has a complaint that is not satisfactorily dealt with by the therapist or the physician, the patient is asked to go and talk to the social worker, who is somewhat aside from the immediate therapy setting. If that is not satisfactory, there is either an institutional committee to hear the grievance, the network will hear the grievance, the State kidney disease commission has people who will hear the grievance. So there are a number of places for it to go, each of which, at a higher level, can then come back to the provider and say your patient has a rational complaint for which you have given no answer.

Senator **Durenberger**. But is the physician really going to bring out this list of where to complain when a patient comes in with a problem?

Dr. **Sadler**. Yes, sir, and in Maryland, as a matter of fact, it is a requirement that patients beginning dialysis receive this in the packet of information. I guess I might further point out that when you ask the patients, were they told these things, that it is not really fair to ask. At the time they begin dialysis they don't feel like listening to a lot of information. A great deal is told them, and then we forget to repeat it when they are in a better frame of mind to receive it. I think we have to be careful of that. But the information is often provided, but provided at a time when it is not perceived effectively.

Senator **Durenberger**. All right. Thank you very much. I appreciate your being here today.

Dr. **Sadler**. Thank you, Senator.

[The prepared statement of John H. Sadler, M.D., follows:]

JOHN H. SADLER, M.D.
Associate Professor of Medicine
University of Maryland Hospital

ESRD PROGRAM OPERATIONS & MANAGEMENT

The Renal Physicians Association has worked with the Medicare program and its end stage renal disease agencies since the inception of Medicare coverage for patients with chronic renal failure in 1973. In the span of eight years, we have seen multiple organizations and reorganizations of this program; first, the fight between the Social Security structure containing Medicare and the former "Health" side containing the other regulatory bureaus; then, the creation of the office of End Stage Renal Disease in each of those bureaucracies and the competition between them; later, the development of the Health Care Financing Administration, the establishment and reorganization of the office of Special Programs, and the erratic but frequent turnover of officials in those offices. There has been competition for policy and operational authority which led to inaction or inconsistency at levels below the policy makers. The unmistakable hope of the leadership of the federal health establishment is that the ESRD program become invisible.

We have complained that the district offices - even the regional offices- have been ignorant and have exhibited little concern for the ESRD program, often saying that it reflected only a small portion of Medicare's total expense and was of little importance; this, despite its uniqueness, its specific establishment by the Congress, and the life-sustaining character of its care.

In developing a management system for a new or different program, or in reorganizing to solve program problems, the agencies have not exhibited creativity or new initiatives, but rather have attempted to force the program to fit policies developed for other programs with which they were familiar and more comfortable. Particularly on the part of the Bureau of Program Policy, there has been distrust, resistance, or uncooperative silence toward every attempt to confront ESRD realities by innovation. This attitude was overcome by Mr. Wolkstein at first, but since his leaving, this uncooperative, rigid posture has worsened progressively. The BPP has thus been able to harmstring ESRD operations and frustrate the few knowledgeable staff who tried to respond to problems.

So much counterproductive and antagonistic action by the Bureau of Program Policy cannot be accidental. The failure of the ESRD program to be effectively directed, documented, or assessed is the failure of the Bureau of Program Policy.

Congress established this program to provide universal access to dialysis and transplant services for all Americans with chronic, permanent failure of their kidneys. That purpose has been fulfilled. We must not lose sight of that achievement. We must also recognize that what we have accomplished is not unique in the world; every industrialized nation from Japan to Italy to Canada has done the same for its people. At the time the ESRD program was established in the United States, there was little data to guide us in predicting the future. The prognostications on which the program's financial estimates were based turned out to be extremely conservative and now appear unrealistic. Now the providers of care find themselves in the position of being the unwelcome bearer of bad news: There are more patients than anticipated. The aggregate cost of their care is high. The physician community did not create the present economic crisis nor the renal disease that it treats.

Fortunately at the beginning, though we had very little data, the choice was made to pay a "screen" rate for dialysis service unless a cost accounted request for a higher exceptional rate was justified. That method has been remarkably effective. The great majority of dialysis treatments provided in America are still provided for that fee. The standard charge for dialysis has not been increased since 1973. Cost containment through that mechanism for eight years cannot be denied. Current struggles within the Department of Health & Human Services - searching frantically for a question that will justify the answer, "lower the screen rate" - simply points up the result of overall searching for cost containment, not a rational justification for proposed reductions in an existing charge. The initial charge was based on a system in which most patients received hemodialysis treatment for seven to ten hours twice weekly. Today, dialysis is most often provided three times a week for four or five hours. That change has increased the number of dialyses and has permitted efficient functioning within the previously established charge. The only rational option for changes in payment is holding to the existing rate until proper accounting justifies the change. Without information, no decision is justified.

The program is not well-controlled or well-documented. We have already mentioned the lack of consistent, knowledgeable leadership or of adequate authority for program leadership. The second principal failing of the program has been the inability to acquire solid data on operations which allows assessment of current program activity and rational projections for the future.

Initially, consultants from the provider community recommended to ESRD staff that the bills submitted for payment contained information to justify payment for services and could be utilized as vehicles for submission of hard data on patient care. That data could then be tabulated to track patients, to delineate patterns of care, to characterize the services provided, the associated morbidity, and through the absence of morbidity and stability of services, positive evidence of quality of care. The Renal Physicians Association believes that only a tabulation of outcome of therapy will provide clear evidence of the quality of therapy. Those initial recommendations were not taken, apparently because the government does not adequately control its Medicare intermediaries to require them to handle this data - and no other satisfactory mechanism was developed. Multiple agencies have attempted to create periodic surveys which have been burdensome and incapable of verification. They have produced a large body of data which is of so little validity that it receives no respect or utility.

In the past two years, the 32 networks of ESRD facilities have been asked to collect data. They have served as the vehicle for transmission of a semi-annual survey and have arithmetically validated those surveys. They have attempted to obtain, each network by its own mechanism, patient tracking data to characterize system function and to permit projections. Because of the smaller scale of the duties of each network, a greater level of success has been accomplished than in the past, but the quality and quantity of information continues to be generally inadequate.

The lack of a foundation of operating information and the lack of systematic management permit a single consultant to tip the balance of program management in whatever way his personal beliefs would bend it. The next consultant, not agreeing, tips it yet a different way. The providers struggle to remain in the program's focus. Patients find that the structure of reimbursement for their care and the forms accompanying it - and they must receive that care to survive - offers paperwork and delay instead of direct knowledgeable support. Inconsistency in management and inconsistency in handling reimbursement issues have been the only constant in this program.

The Renal Physicians Association will attempt to address the specific questions presented and will expand these comments following interaction at the hearing.

UTILIZATION AND ACCESS

1. Do the existing minimum utilization rates reflect current accepted medical practice? Are they being applied in a reasonable manner? Are they needed to control the cost of the program and/or the quality of care?

R. Minimum utilization rates have been suspended since they were an insignificant characteristic of facilities as they currently function. They have played no role in program assessment, control, or cost containment. There is no evidence that they impact on quality of care or cost, despite the theoretical appeal of regionalization and control.

2. Does the certificate of need requirement effectively control the cost of the program and/or the quality of care? Is the requirement necessary? If the requirement is eliminated, what would be the effect on the cost of the program, quality of care, and patient access to facilities and physicians?

The certificate of need process is cumbersome and varies among states. It may not be the best design by which to plan for facilities to satisfy a need, but some systematic ordering of facilities is desirable, since this is a complex service and should not be provided at random. The necessity for continuity of care anf for interaction among facilities carrying out different levels of care so the patient will have access to all levels of care requires structure. The systematic nature of the levels of care makes it unlikely that a patient could competently shop for a treatment facility.

The federal role in health planning has principally been one of providing somewhat greater uniformity in the states' planning processes and through that, possibly, a less politicized and fairer approach to health planning.

The Renal Physicians Association recommends that some structure and the planning continue in ESRD facility authorization. We recommend that such activities utilize well-informed providers as well as consumers in the assessment of specific proposals and general planning policy.

3. What barriers restrict patient access to facilities and physicians of their choice? What barriers restrict access to home dialysis and to transplantation? Should these barriers be eliminated? And if so, how?

R. There are no systematic or programmatic barriers to access as a general rule. Geographic problems are the principal ones. There may be specific instances under exceptional circumstances, but patients generally have access to multiple modes of therapy at their choice. Access to transplantation depends more on medical and scientific developments in organ procurement and in transplant therapy than regulatory factors. Similarly, utilization of home dialysis is not limited so much by access as by the need to develop informed and motivated patients who will seek the liberation of home dialysis. These approaches are not effectively encouraged by program policy and regulation, but earlier inappropriate policies did indeed make them less desirable to patient and provider.

4. Should patients be free to choose a physician independently of their choice of treatment setting? Should the program be modified to foster open market competition among providers of treatment?

R. ESRD programs need to be cohesively directed with consistent policies and procedures. Patients and physicians need to participate in a treatment program in continuity. Patients are guaranteed their right to choice of physician and treatment within the limits of appropriateness. The idea of "open market competition" would create anarchy in the provision of a complex chronic service which requires specially trained individuals. RPA does not see that as a practical option.

5. How does the United States experience with home dialysis, transplantation, and other treatment modalities compare with other countries?

R. The United States experience with home dialysis, transplantation and other treatment modalities varies in degree from other countries, but not in general character. The following tabulation of programs from other countries points out some of the variations. Note that population in northern Europe where the genetic base is smaller and overall kinship somewhat greater have a higher success rate for transplantation and thus a somewhat higher frequency of transplantation. In southern European countries and in Japan, dialysis units are large, transplantation is still limited and home dialysis is less common than in the United States. In those countries in which there is a higher level of education and a tradition of work ethic and independence, home dialysis is more readily undertaken.

	Total Dialysis patients	Home Hemo	PD	Transplant
USA	52,364	4,715(9.01%)	2,946 (5.63)	4,697 (8.97)
Canada	2,918	539(18.5)	590 (20.2)	
Europe (total)	75,000	12,000(14.1)	2,000 (2.35	
		- 47% -		
Switzerland(6.3M)	971	189(19.46)	76 (7.8)	
Denmark (5.1)	470	97(20.6)	31 (6.6)	
United Kingdom(55.9)	3,465	1,956(56.5)	335 (9.67)	
France (53.3)	9,217	1,545(16.8)	373 (4.05)	
Spain (37.1)	4,415	260(5.9)	-	

	Transplants/Million/Year
USA	21.35
Australia	21.9
Canada	16.2
Finland	28.0
Sweden	27.0
Switzerland	25.0

PROGRAM MANAGEMENT

1. What effect have prior reorganizations had on the management of the program? Will the current reorganization adversely affect the program? Should there be a focal point for the program?

R. Reorganizations, as discussed before, have been critically disruptive to consistent knowledgeable leadership of the program. Diffusion of policy and operational authority, separation of different aspects of program operations into different divisions of HCFA have led to narrow, rigid, and inappropriate policies. A loss of a sense of direction is the result of unclear or inadequate policy decisions.

The currently projected reorganization will worsen these conditions further. The existing office of End Stage Renal Disease has been shrunk to near vanishing. It had accumulated a number of people who had learned the program and who were capable of prompt and well-informed responses to questions. The OESRD did not have adequate authority , staff or mission to really direct the program, but it was a focal point at which information could be assembled, problems defined and solutions sought. With no focus for the program, the problems that develop will be slower in definition and much slower in resolution. The questions and complaints will come into multiple HCFA offices and create an undirected disturbance in general HCFA operations.

If the ESRD program is to be coordinated and directed, it is essential that someone with authority and knowledge be in an identified office to carry out that function. All efforts to avoid this are attempts to remove the identity of the ESRD program to avoid accountability or the operational shambles resulting from failed policy and fragmented direction.

2. How well have the intermediaries and carriers performed under the ESRD program? Who is responsible for assessing their performance under the program and by what mechanisms? How can the effectiveness and efficiency of intermediary and carrier ESRD operations be improved? Should their ESRD operations be consolidated?

R. There is enormous variation in the quality of intermediary functioning. There is an office in HCFA which is responsible for evaluating intermediaries and their assessment, if done, is not made public. Results of intermediary function indicate that no specific ESRD factor contributes to intermediary evaluation. Data handling for ESRD beneficiaries could easily be an essential evaluation tool and have an impact on the assessment of an intermediary. Intermediaries appear to consider End Stage Renal Disease a non uniform part of the Medicare program; a nuisance which receives only the attention which is unavoidable. The suggestion that ESRD intermediary function be consolidated in a single or a small number of regional intermediaries has merit. It would require coding of ESRD beneficiaries, but it would permit the scope of ESRD affairs in an intermediary to become sufficiently large to justify adequate staff and adequate training so that the intermediary could handle the data, could be promptly responsible and could provide some service in coordinating program activities. As an alternative proposal, RPA suggests that through the same coding of ESRD beneficiaries, it would be possible to permit ESRD facilities to use any intermediary they choose. They would be expected to select one whose effectiveness earned their patronage. This could provide for effective competition among intermediaries, appropriate reward to high quality intermediaries and resolution of problems in those which do not now function effectively.

3. How is program integrity assured? What are the results of recent studies by the Bureau of Quality Control? What has been done to identify program fraud and abuse? What are the most serious issues related to program integrity, and fraud and abuse?

R. This question cannot be specifically adressed by the Renal Physicians Association since investigations of the program are not available to us. We would like to make two points nonetheless. First, as in the overall Medicare program there may be fraud and abuse in the ESRD program, but we believe it is a very small fraction of total operations. We also believe that fraud and abuse should be dealt with by the same mechanism as in the overall Medicare program and should be prosecuted vigorously when the findings justify it. We object the selective leaking of damaging data to the public press for this impugns the character and reputation of all ESRD facilities through innuendo rather than punishing the violator through legal handling of factual reports. The Renal Physicians Association supports efforts to discover and punish poor care and overcharging.

Secondly, when studies of the ESRD program or investigations of facilities are undertaken, we urge that they be carried out after objective planning and definition of purpose. They should be undertaken by objective responsible competent individuals, performed accurately and the results subject to review and response. This has not characterized studies done to date. They are frequently political, self serving, incomplete, misleading and generally not capable of verification or of satisfactory rebuttle. When a study is undertaken with its conclusion in hand, the findings are selected to fit.

This again points out the weakness of the program through the absence of proper data collection, which would usually eliminate the need for studies other than appropriate aggregation of data.

4. What have the networks accomplished? How effectively have they adressed quality of care, treatment setting, and treatment modality issues?

The Renal Physicians Association believes that ESRD networks were a rational attempt to assemble knowledgeable professionals for collaborative program assessment and planning. These same functions, however, were granted simultaneously to HSAs, PSROs, and SHPDAs. These general agencies have had overruling authority and have undermined and discouraged the members of networks, limiting their effectiveness.

5. Are networks needed to collect data, ensure quality care, or participate in facility planning? Are there alternative methods to carry out these functions? Should network operations be consolidated or eliminated?

R. The networks are presently collecting data which, as adressed before, is somewhat better than previously acquired on a national scale. Individual patient tracking data is not being uniformly acquired or stored by networks. State programs, local forms and network data collections overlap and sometimes conflict with Medicare ESRD forms. Systematic direction is lacking.

If networks are to be well utilized in the future, they must be given authority to carry out actions which do not overlap with those of other agencies. Presently, the networks are not even capable of being held accountable. If the networks cannot be used effectively, there is no reason for them to continue. If they do not continue, some other mechanism must be found to collect data and to provide for local collaboration in assessment of ESRD affairs and quality of care beyond the capability of existing HSAs and PSROs.

QUALITY OF CARE

1. Are facility certifications and on-site annual surveys necessary to assure quality care? Are these less costly alternatives to the facility survey and certification process?

R. Surveys do not need to be made annually but occasional on-site surveys are useful in assuring the quality of care. If adequate program data existed, it would provide the mechanism for targeting those facilities which require an on-site survey and would, through the outcome of care documented in data collection, provide an assessment of the service provided by each facility. This documentation would eliminate the need (and the expense) for regular on-site surveys in detail.

2. What deficiencies have been identified through the survey/certification process? How many facilities were not certified or were decertified? For what reasons?

R. The Renal Physicians Association has no information.

3. How should quality of care be monitored? What data is needed to assess quality?

R. The Renal Physicians Association believes that data provided to document the service for which payment is requested, obtained serially, will track the care of each individual patient. These data could then be aggregated to provide an excellent assessment of the outcome of patient care, of facility performance, of patterns of care, and finally,of cost. This data can be obtained from the existing bills if the patient receiving ESRD services has a specific code and if the agency receiving the bills has the requirement to tabulate this data appropriately. Since there is no such mandate upon the intermediaries, it has not been previously done. The RPA believes this tabulation of data would provide the most dependable and economical basic system of quality care assessment. Review of this data would require a very limited use of labor intensive site visits and peer review. All forms of review are costly and if the program is not willing to pay for review, it is not goint to get it. The Renal Physicians Association wishes to point out that quality of care is different from the price of care. Conversations with HCFA officials make clear that many of them do not understand the distinction.

4. What staff qualifications and/or training are needed to ensure quality care? What levels of staffing are necessary to provide adequate care?

R. The Renal Physicians Association has developed a position on staffing in dialysis facilities. We believe that different levels of care are provided in different facilities and that staffing should be appropriate to the level of care in a given facility. The one invariable in all forms of ESRD care must be appropriate overall program supervision by qualified physicians. All ESRD care requires continuity of participation of social workers and dietitians as well as nurses and physicians, and all programs require backup from a comprehensive health facility.

PROGRAM DATA AND RESEARCH

1. Does the medical information system provide useful, accurate, and complete data to program managers? Is reliable and complete reimbursement, cost, treatment modality, and patient characteristics data available in usable form?

R. The Medical Information System has already been discussed in response to other questions above. It is inadequate and ineffective.

2. How can the data for effective program management be collected? What sanctions are available to assure complete, reliable data are provided?

R. Data collection through the billing process, either through a small number of larger intermediaries with specialized function, or through some other mechanism is recommended. The appropriate sanction is that bills not containing the data not be paid.

3. How should clinical research data needs be satisfied?

R. The Renal Physicians Association believes that clinical research and basic research into the causes and treatment of end stage renal disease are essential to real economy. Only through improved knowledge of disease and improved treatment will we lessen the need for dialysis and transplantation and reduce the cost of expensive high technology.

The RPA further believes that data needs for research cannot be assessed until the functional data on patient care is acquired and tabulated. Additionally, we believe that NIH and HCFA should be encouraged to support studies related to end stage renal disease rather than assuming that this form of disease and its therapy are static and incapable of significant improvement by greater knowledge.

4. What is the status of the studies and experiments mandated by P.L. 95-292? How many agencies are involved in these studies and experiments? How are their efforts coordinated?

R. The Renal Physicians Association does not have knowledge of the status of all the studies required by Public Law 95-292. We would like to point out that the one important study completed of those requested is the evaluation of reuse of consumables. A review of the literature, in vitro testing of procedures, and survey of reuse practices were carried out on contract through NIADKD. Dr. Norman Deane, President of the Renal Physicians Association was also the principal investigator and will report separately on that study.

Through the National Center for Health Care Technology, that study and other data will be assembled in a conference in November of 1981 to establish as nearly as possible the state of the art of reprocessing consumables in hemodialysis.

5. What studies and/or experiments are the most promising with respect to reducing program costs and/or improving quality of care? Have they been given priority?

R. The assessment of reuse of consumables offers an obvious opportunity for some saving. Appropriate harvesting of data on the program will permit a great deal better assessment of present practices and could save significant amount of money in the cost of program review.

A focused effort on disability assessment, compensation assessment and rehabilitation programs holds the potential for an improved quality of life as well as cost saving for ESRD patients.

Thank you Mr. Chairman. The Renal Physicians Association appreciates the opportunity to present its position. We will expand on them if appropriate after this hearing and we will stand ready to respond to questions in the future.

RECOMMENDATIONS

The Renal Physicians Association recommends:

1) that an office of End Stage Renal Disease with experienced personnel and authority for program management be established. It should have both policy and operational authority.

2) that a data system based upon individual patient data, collectable from service billing and accumulated by the intermediary or his agent, be set in place to provide patient tracking and clinical outcome data which will provide for assessment of quality and efficiency of care. This requires ESRD patient coding and special transplant followup forms.

3) that studies of this program be planned objectively, be carried out accurately, and then subjected to knowledgeable review. Such studies may then be used for program purposes and development of positions and policies. No studies should be leaked piecemeal to the public press, but may be made public after review. Investigation of possible fraud and abuse should be carried out by standard techniques. Prosecution should be pressed vigorously where justified.

4) some planning and coordination mechanism is needed for complex facilities. "free market competition" is not a useful primary concept in this environment. The necessity for coordination of facilities for continuity of services requires some planning. This should not be interpreted as a commendation of existing health planning agencies.

5) appropriate research should be supported and encouraged to provide new knowledge for improved quality of care and ultimately, for reduction in the need for ESRD care, the source of saving money and improving quality of life.

HEARING ON THE END STAGE RENAL DISEASE PROGRAM

SUBCOMMITTEE ON HEALTH

SUPPLEMENTAL STATEMENT

RENAL PHYSICIANS ASSOCIATION

We normally do not comment on the testimony of other organizations before Congressional Committees, but the testimony of the American Association of Nephrology Nurses and Technicians stated positions so extreme and potentially so detrimental to the End Stage Renal Disease Program that response is necessary.

The AANNT recommends a position which isolates the patient from the physician and is not in the interests of the patient. The Renal Physicians Association has outlined the role of the nephrologist in the care of the ESRD patient on maintenance hemodialysis treatment. The constellation of abnormalities presented by the ESRD patient requires day to day supervision by the nephrologist.

The AANNT suggests that nurses assume the day to day medical supervision of the ESRD patient. We must emphasize that the day to day care of chronically ill patients involves the practice of medicine and the practice of medicine is restricted to physicians. By implication, AANNT would like to redefine what the practice of medicine entails for the benefit of nurses; however, we would suggest that such parochial advocacy is more appropriately directed to State legislators who have jurisdiction over the licensing of professionals such as nurses and physicians.

The AANNT statement addresses the certificate of need issue as categorically being costly and ineffective. Although we recognize the difficulties which have been presented for an accurate assessment of the value of certificate of need programs in health planning, it is clear that there have been some studies which demonstrate its cost effectiveness in controlling hospital expenditures and avoiding duplication of facilities.

SUPPLEMENTAL STATEMENT

RENAL PHYSICIANS ASSOCIATION

The matter of staffing for dialysis facilities must be considered principally within the context of quality of care. The AANNT takes a strong position in favor of open staffing for dialysis facilities as a prerequisite for patient access. Since quality of care is the critical issue in this area, we consider that the decision regarding staffing patterns should be determined by the highest level of quality of care that can be achieved in any particular program. In some instances, this might necessitate a closed staffing pattern while in other instances an open staffing pattern may be required. This is the basis for the position of the Renal Physicians Association that the issue of facility staffing must be left to the individual facility Governing Board or responsible parties who undertake and are required to provide the highest possible level of quality of care.

Senator DURENBERGER. Our next witness is Dr. James Cerilli, professor of surgery, past president of the American Society of Transplant Surgeons, from Columbus, Ohio. Welcome, Doctor.

STATEMENT OF DR. JAMES CERILLI, PROFESSOR OF SURGERY, PAST PRESIDENT, AMERICAN SOCIETY OF TRANSPLANT SURGEONS, COLUMBUS, OHIO

Dr. CERILLI. Thank you very much, Senator Durenberger. I am pleased to be here. I certainly would like to thank Congress really for the foresight that they showed several years ago in making it possible for tens of thousands with end-stage renal disease to now be alive.

You have a difficult problem, and that is how to allocate Federal resources. You have to decide between maybe dialysis for all and maybe food for the children at lunch time.

I have a problem. My problem is to be sure that in 1990 that all patients with end-stage renal disease have the same access to care that they have in 1980, and that we preserve this access to care. Because right now, for the most part, most patients do indeed have access to reasonable care.

The threat to this, as we are all aware, otherwise we wouldn't be here, is the cost of this program. How we are going to preserve this for the patients in 1990; my children, our grandchildren?

In order for me to present really my views on this, certain basic facts I think must be transmitted to the group.

First of all, we do have data about transplantation. Patient survival now—and this is a conglomerate of eight centers, the University of Minnesota being included, sir—that shows patient survival after renal transplantation is now approximately 90 percent. The graph survival when we take kidneys unrelated is about 55 percent. When we take it from liver-related donors, it is about 75 percent. And with the new techniques that were instituted under the foresight and the excellent program of the University of San Francisco, liver-related donor transplantation is now approaching 90 percent in terms of graph survival.

Senator Durenberger. Excellent.

Dr. Cerilli. Dr. Blagg's data was published several years ago from a northwest kidney center and shows the comparable data from a tally of rates, basically home dialysis patients, and our data in other centers would tend to agree with this; namely, it is a continuing decline in patient survival. So that about an 8-percent mortality rate per year is what one can expect from dialysis patients. These were mainly home dialysis patients.

[Showing of viewgraph.]

Dr. Cerilli. Now the goal of this program should be rehabilitation. It is not to keep patients on the machine, it is not to transplant them. The goal is to rehabilitate them. There is some pretty recent data about rehabilitation, much of which I must admit comes from the University of Minnesota with Dr. Simmons.

The Duke group, the Minnesota group, our group, the Breathen group, have all showed really that the rehabilitation rates on transplantation for successfully transplanted patients is about 70 to 80 percent. For center dialysis patients it is about one in three.

[Change of viewgraphs.]

Dr. Cerilli. Now one of the reasons we are here, obviously, is because of the cost of the program. I think it is very important to have a perspective of the relative cost with the various modalities of care. I am going to do that very, very briefly because I think it is germane really to the issue.

If you transplant a hundred patients and follow them for 10 years, how much does it cost? Well, if you assume that 60 percent of the graphs work, and that is realistic with the data I just gave you, 60 percent; it's $20,000, and you saw Dr. Davis' figures of $20,000 is about realistic, times 100 patients is about $2 million. Now you have got about $1,000 per year times 9 years, times the 60 patients whose graphs worked, is about half a million dollars. Then you have got to add in the dialysis cost of those graphs that have failed because that is really transplant cost. You take $28,000 a year, which is about center dialysis cost, times 9 years, times 40 patients, is over $10 million. You add it all up, $12 million to transplant 100 patients and follow them for 10 years.

Now let's put them on center dialysis.

[Change of viewgraphs.]

Dr. Cerilli. You put these 100 patients on center dialysis, at $150 per treatment, which is about what it is now, times 3 treatments a week, times 52 weeks, plus the vascular access and hospitalization, it is about $28,000 per year, times 10 years, times 100 patients, $28 million to keep 100 people alive for 10 years. Now you subtract that 28 from the 12 and you come up with a saving of about $15 million.

Now if dialysis were necessarily better rehabilitative more at a higher survival, then I would say it is your job to come up with the money. But, nevertheless, it is not. Transplantation for those medically suitable is the answer for end-stage renal disease.

Now we have got some problems. And what are some of them?

[Change of viewgraphs.]

Dr. **Cerilli**. Well, the problems are that in some of the directions that have been proposed, there is going to be an enormous erosion of the utilization of transplantation services. Why? Well, if you deregulate this system you are going to see an unbelievable proliferation of dialysis, and particularly dialysis units, and some transplantation units, because the States simply do not have the financial motivation to control cost. Now there are some that do, but most of them do not.

They will make decisions about the number and size and location of facilities based not upon financial incentives but simply what is locally political expedient. I have seen it time and time and time again.

[Change of viewgraphs.]

Dr. **Cerilli**. Now quality of care does relate to the proliferation of units. There is no question that this proliferation of dialysis units and transplant units lead to poor care. This has been documented by at least three major studies: the Stanford group, using open heart surgery, showed that mortality rates were higher, morbidity rates were higher in small units compared to large; the study from Manchester, England, using transplantation, showed that mortality rates were higher, and morbidity rates were higher in transplantation with the small units as compared to the large; and, thirdly, the American Society of Transplant Surgeons did a similar study. Smaller units are not conducive to quality care. If you deregulate, you proliferate the units, and you will either decrease quality care, and that care is expensive.

Now there is a more insidious and, unfortunately, really present issue about proliferation of the units. If you proliferate dialysis capability, what happens is that you utilize that capability. The more dialysis stations that you provide, those stations have a way of getting filled.

Now the motives, I don't think you need to go into; it is simply a fact of life.

Unused capability inhibits the referral of patients into cost and medically effective transplantation and cost and medically effective home dialysis.

Now you have got a problem. How are you going to utilize the dollars? One way you could do it, you could simply say, we will spend a billion dollars. We will take the number of patients, and we will give them each $50,000. When it is gone, it is gone. We will provide a major medical policy, just like many of the major medical policies. But that is unfortunate because some people don't have a disease process that makes them eligible for some of the most cost-effective forms of therapy. But what you could do is you could say we will give you $50,000. When it is gone you are disenfranchised for a year, and then we will put you back on the program. That would stimulate cost effectiveness. But, nevertheless, it still would provide a point in time when the patients would not be covered.

Now the other option is to let the States do it. That will be a catastrophe unless you give the States the money. Because there will be no motivation at all for the States to do this in a cost-effective way.

[Change of viewgraphs.]

Dr. CERILLI. So my recommendations are, is you have a network system; it is not perfect; it is far from perfect. They are learning their role just like many other people learn their role and it takes time. But they are beginning to do a pretty good job of trying to keep costs down in terms of assuring quality care and trying to keep down the proliferation of units that leads to bad and expensive care. They are just getting started. It is like condemning the Reagan economic program before it ever got started.

The networks are comprised of very, very inexperienced people, but they are learning and they are getting better. Right now it is the simplest and most effective mechanism you have for trying to keep a cap on this course. It is pretty cheap. It is less than the cost of 0.2 percent, about 200 dialysis patients.

[Change of viewgraphs.]

Dr. CERILLI. In conclusion, what I would like to say is I think, really for medical reasons and for cost effective reasons, transplantation should be encouraged. I think you must avoid proliferation of facilities for the reasons that I mentioned. It is cost ineffective and it is poor care.

I think you should support the network role in certification because, unfortunately, the HSA's do not have the expertise to do it if they survive. The States do not have the expertise in most States to do it and their regulatory mechanism is often outmoded.

But the networks bring together a voluntary group of people at low cost to provide expert opinion to HCFA. HCFA is doing a better job than it did a few years ago, but you have got to give them a chance.

You have got to update the regulations to support the goals of one, two, and three.

Senator, this program has done marvelous things for thousands of people. You have got a crossroads. Depending upon the direction it takes, it is either going to get better or it is going to fall flat on its face. And the options are there. I think the decision is a very difficult one, but I think the information is there to make the right one. Thank you.

Senator DURENBERGER. Thank you.

Let me ask you to put the last chart back up so I can ask Dr. Cerilli a couple of questions.

[Change of viewgraphs.]

Senator DURENBERGER. How would we encourage transplantation? I just heard that one of the difficulties is that patients on dialysis see transplantation failures coming through dialysis and consequently feel they should hang on to what they've got.

Dr. CERILLI. Yes, sir, that is true. I think the patients had a suggestion, that is, better information to the patients in a continual process is important. The second is not to set up a reimbursement system, as has been suggested, I believe, and I am not familiar with the details. But it is my opinion that what I have heard of the proposed reimbursement system, it would be detrimental to transplantation because, although there is nothing necessarily wrong with home dialysis, it would tend, for financial reasons, to support home dialysis over transplantation. And, really, I think with a given patient, medically suitable, transplantation is more medically and cost effective. But you are going to set up financial incentives that would steer that patient toward home training, and that might not necessarily be the best thing for him.

We need a program that would stimulate organ retrieval. Representative Crane, for instance, has introduced a bill in the House to try to stimulate organ retrieval via tax credits. Granted it is only a beginning, but it is an idea by which everybody benefits, the patient, the Government, everyone.

So there are mechanisms, both regulatory and legislative, that can improve and encourage transplantation.

Senator DURENBERGER. Let me address the issue of facility proliferation. Am I accurate in stating that you feel the system encourages the proliferation of capacity, and that that capacity will be utilized?

Dr. CERILLI. Yes, sir, there is no question about that. The HSA, which is currently part of the decisionmaking process, will act primarily on local political needs and pressures. They have no basic concern really, although there are many people for the cost of the program. That is not their money.

In States, like many States, the issue is the same. I have seen it time and time again in Ohio and the network with which I am chairman. They are not spending their money. It is easier to say yes. It is difficult to say no. The only reason to say no is if it is costing you something. It is costing them nothing.

Right now the only regulatory governor or governor in the system is the networks providing the expertise into the HCFA regions. I am the first to admit that it is not perfect and they are just learning their process. They are, in many areas, still very immature. But they are growing in maturity. I think, given an opportunity, it is your best system for the least dollars.

Senator DURENBERGER. Let me address the certification process, which as I understand it, is typically designed to limit capacity in the system.

In general, I believe in competition and feel that excess capacity is necessary because it makes choices available to people and leverages the entire system. Although there may be something unique about the ESRD system, I think many of these principles could be applied.

I understand what you are saying in terms of the effects of deregulation, but suppose we change the system and provide two important things to persons with renal disease; we provide them with the money and we provide them with information. If they go into the community you have just described with those two important factors—money and information—what will the effect be on providers, equipment, and facilities?

Dr. CERILLI. Well I think if you provide it to the patient directly then he will seek out a very cost-effective form of therapy. I think if you provide it to facilities, then you have an explosion of dialysis units, which will tend to become full. I think that that is one of the reasons why this country, for instance, has gone the route of center dialysis and has not gone the route of many of the European countries of home dialysis and transplantation.

We have provided all that center dialysis capability and it just tends to get full.

Senator DURENBERGER. Are you saying that if we provide patients with the financial wherewithal and the information to make a choice that we may be able to overcome some of the problems that you see out there?

Dr. CERILLI. Yes, sir, I think you do, if you provide it directly to the patient.

Senator DURENBERGER. This will be the last question because of time. On the whole problem of information, whether it is information about the nature of the problem that people have, the treatment alternatives, the cost, the accessibility, or whatever, who do you think should provide that information? Should it be providers, patient advocacy groups, intermediaries, the Government, or perhaps some other source?

Dr. CERILLI. Well let me provide you with an example to answer that. The University of Minnesota, like, say, my university, that information comes to the patient and to the doctor by peer pressure and exposure to alternatives. The patient sees home dialysis. He sees self-care dialysis. He sees CAPD. He sees transplantation. I have resident nephrologists all around me, that I peek over their shoulders like they peek over mine. It is an internal peer review, internal information system.

Unfortunately, not all programs have that depth, and the smaller they get, the less depth they have. The less depth they have, the less that internal informational system is effective.

Now the networks help meet some of that gap, because the nephrologists and the patients who are representatives hear about the fact that you should transplant diabetics, because it is the treatment of choice. Where many nephrologists will be telling that patient, no, that isn't true. But it is. They hear the alternative points of view within the network setting. Right now that is about the only form you have. The HSA's don't provide it. The States certainly don't provide it. Where else is it?

The only form of internal peer pressure or informational system that is now in place is that council of the network program. It has many problems, but it is helping them to provide that need.

Senator DURENBERGER. Thank you very much for your testimony. I appreciate it.

[The prepared statement of G. James Cerilli, M.D., follows:]

ALTERNATIVES FOR THE ADMINISTRATION OF END STAGE RENAL DISEASE

by

G. James Cerilli, M.D.

Ther is no question that there are thousands of patients with end stage renal disease who are alive because of the financial support given them through Medicare via legislation enacted by Congress in the early 1970's and revised approximately three years ago. This original legislation which was far reaching and far-sighted has made it possible to treat patients who would otherwise be denied access to medical care. Since that time there have been enormous changes in not only the medical approaches to end stage renal disease but in addition much has been learned as to the optimal administrative mechanism by which this care can be delivered. In order to provide a background upon which to support my position, I wish to provide you an overview of the current status of renal transplantation and dialysis. There has been enormous progress in the application of renal transplantation to the management of end stage renal disease. Based on a study of the American Society of Transplant Surgeons in which the Society evaluated the results in 1978 and 1979 from eight major transplant centers, it is clear that the mortality rates (i.e., the chance of dying after renal transplantation) has dropped precipitously to approximately 5% and in some larger centers it is less than 2%. In addition, the chances of a kidney graft functioning have also improved based upon the utilization of new immunosuppressive techniques and the more appropriate screening of donors. With living related donors one can now expect over 90% graft survival and with cadaveric grafts (i.e., from recently deceased individuals) one can expect graft survivals of approximately 50%. Following successful transplantation at Ohio State University -- and this is similar to many other Centers -- 80% of patients with a successful kidney transplant return to work or education, thus resuming a relatively normal existence not being dependent upon social programs for their financial support. Hemodialysis, which is an enormously beneficial form of therapy and without which thousands of patients would no longer be alive, however, has certain innate disadvantages as compared to transplantation. First of all, the mortality rates with hemodialysis average approximately 8%

per year in patients under the age of 55 as evidenced from analysis of our own data at Ohio State University and from a large series from the Northwest Kidney Center in the State of Washington that analyzed a series of patients under the age of 55 who were non-diabetic and most of whom were on home dialysis. Thus, the chances of dying are higher on hemodialysis than they are with a kidney transplant. Secondly, a recent article in the New England Journal of Medicine as well as our own data indicates that only one-third of patients on hemodialysis are successfully rehabilitated. The remaining two-thirds often require financial support from one of the many social programs that are available. Thus, a much lower percentage of hemodialysis patients become productive members of the community, are paying taxes, and contributing to the costs of their medical care. Thus, from the point of view of rehabilitation and mortality, transplantation now is clearly, particularly for the patient under the age of 55 or 60, the optimal form of therapy from a medical point of view. Now there is another, and, unfortunately, very important difference between these two forms of therapy and that is in their costs. In order to illustrate this, I wish to present a comparison of the costs of 100 patients who receive a kidney transplant as compared to 100 patients who are maintained on Center (i.e., facility supported) hemodialysis. This cost comparison includes the cost of the initial transplant plus ten years of follow-up as compared to 100 patients who were treated with center hemodialysis for ten years. Based on figures accumulated by the End Stage Renal Disease program, the initial cost of a renal transplant is approximately $20,000 and each year afterwards averages $1,000. If one assumes only 60% of the kidney transplants function and the remaining 40% of the transplant patients return to center hemodialysis, the total expense of transplanting 100 patients (includes transplant costs and follow-up costs of dialyzing 40 graft failure patients for 9 years) is approximately $12 million. It costs $12 million to transplant 100 patients and follow them for approximately 10 years. When one compares this cost to that of hemodialysis, the difference becomes quite noticeable. Hemodialysis now costs about $28,000 per year per patient.* Multiply $28,000 times 10 years of therapy times 100 patients and it totals $28 million. This point must be emphasized. It costs $28 million to keep only 100 dialysis patients alive on center dialysis for ten years. Only one-third at the most, of these patients, are rehabilitated based on analysis of our own data of male patients under the age of 60 and that from Duke University.

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*$150 per dialysis x three dialyses per week x 52 weeks per year plus costs of vascular access and hospitalization

Cost-savings, therefore, of transplantation as compared to hemodialysis is over $15 million for simply 100 patients.

I therefore have described to you a medical and economic scenario in which transplantation for patients under the age of 55 or 60 is not only the most medically-effective but certainly the most cost-effective form of therapy. Now, if this is true, what is the problem with the current relationships between the federal government which supports this program, hemodialysis, and transplantation? The problem is very simple. We are all aware that the costs of this program are becoming astronomical and are predicted to reach about $3 billion in 1983-84. There is no question that a significant portion of this cost increase represents increased numbers of patients that are being treated but there is also no question that part of the increase in these costs are due to an administrative and financial incentives for maintaining patients on center dialysis rather than referring them to the more appropriate and less costly forms of therapy such as home dialysis and transplantation. The primary goal of both Congress and the physician involved in the care of these patients is very simply: no patient should be denied care in the future because of lack of availability of fiscal support. We must maintain access to care for all patients with end stage renal disease and a major threat to this principle is the rapid escalation of costs. These costs have increased both due to an increased number of patients but also because patients receive poor and inappropriate choices of therapy. The proposal that has been suggested by which the end stage renal disease program would no longer be under the regulatory system of the federal government via HCFA and the Networks would clearly increase the number of patients who receive inappropriate and more expensive forms of therapy and the reasons for this position are as follows: If the states are given the authority to choose the number and size of dialysis facilities within their states, the decisions that are made will almost always be politically motivated and dependent upon local pressures as there will be no fiscal motivation for efficiency as the states are not paying the costs. The federal government will be paying the bill through Medicare but the states will control the size of that bill. I have seen time and time again where dialysis units have been approved at the state level purely on the basis of local political pressures with little or no medical need or because of inadequate criteria for certificate of need with little motivation to improve those criteria. If you totally deregulate the system at the federal level and continue to pay for end stage renal disease using the current system, you will have an explosion in the number of dialysis units each of which will be quite small and, thus, cost-inefficient as small units cannot operate as effectively as large units in terms of cost-efficiency. But there is another even more dangerous and insidious hazard to the proliferation of small units. Small units can remain fiscally solvent only if they become larger units, particularly if the payment per dialysis is decreased as is being proposed. This means, therefore, that the flow of patients out of center dialysis into either home dialysis which is slightly less expensive or into peritoneal dialysis which will become less expensive, or into transplantation which is much less expensive, will be markedly inhibited. The small unit must accumulate a large patient base in order to survive fiscally. If you deregulate the system and allow the states to control the number of units within the state and yet continue to guarantee payment on a per patient basis, you will have a rapid increase in the number of dialysis units that will lead to the sequestration of patients away from the more cost-effective forms of therapy such as home dialysis and transplantation. Such federal regulation does cost money but it is worth pointing out that there are current 50,000 patients on hemodialysis and the cost of the Network system under HCFA that regulates this system represents the costs of only 200 dialysis patients per year and is less than 0.2% of the cost of the program. The Networks bring together a large group of specialists in end stage renal disease to address the problems of end stage renal disease and does so mainly with volunteer time and at relatively low cost. If the Network system prevents the unnecessary duplication of facilities it undoubtely represents a worthwhile investment.

In addition to a relationship between size and cost-effectiveness, there is a relationship between size and medical effectiveness. It has been shown by several studies that larger units provide a higher quality and thus less expensive, medical care far sophisticated medically, than do smaller centers. The study from Stanford University utilizing open-heart and total hip replacement surgery as examples, a study from Great Britain using transplantation as an example, and a survey analysis of transplantation results by the American Society of Transplant Surgeons, all indicate that the clinical results in the smaller units are not as good as it is in larger medical units. For instance, the mortality rate in centers performing less than 15 transplants per year was 40-100% higher than in units performing over 40 transplants per year.

Thus, it is clear that the removal of effective federal regulations would guarantee the proliferation of small, economically inefficient, and less medically-effective units. If this is true, are there possible alternatives? You must not, under any circumstances, accept the proposal to return the decision to the states as to how many end stage renal disease facilities will be certified and yet continue to fund dialysis under the current medicare regulations which encourage the maintenance of patients on dialysis. If this is true, what is a reasonable alternative? I would suggest the following: Decide how large a financial commitment this country can make to the management of patients with end stage renal disease. Once this has been decided, divide that number by the number of patients being treated for end stage renal disease and allocate a fixed total amount to each patient and let each patient decide how he would prefer to spend the support he is receiving from Medicare. He may choose transplantation if it is clinically appropriate, home dialysis, or center dialysis. Let the patient be the mechanism by which cost-effectiveness is implemented. This approach is similar to a major medical insurance policy but has the obvious problem of some patients utilizing all their allocation and yet still requiring care. A second alternative would be for the federal government to give each state a fixed amount of money rather than an open-ended account as is the current system. With fixed support from the federal government, the states would then have the motivation to administer this system in a cost-effective fashion. Patients who might not receive therapy will then turn to the states if they are denied care and not to the federal government thus putting pressure on the states to become more cost-efficient or to increase the amount of dollars generated for end stage renal disease at a state level.

On behalf of myself as a director of a transplantation program, chairman of a network, and as Past President of the American Society of Transplant Surgeons, I urge that you carefully consider the fiscal and medical catastrophic implications of implementing a system by which the control of the amount of dollars that are spent for end stage renal disease is determined at a state level while the federal government must provide these dollars. I urge you to devise a system that will lead to the creation of regional centers for the care of end stage renal disease -- both for transplantation and dialysis -- in order to maximize the cost-effectiveness of size and also to optimize quality patient care as demonstrated by results of studies in Great Britain and in this Country. There are currently approximately the same number of transplantation units in the State of Ohio as there are in Canada. West Germany, a Country of reasonable medical sophistication, with a population of approximately 50 million has five transplantation centers; this Country has over 120 transplantation centers. In Great Britain, a transplantation unit serves a population of about five million -- in this Country it serves about one and one-half million. These countries have recognized the advantages of regionalization of health care for complicated medical problems and I urge you not to adopt legislation that would aggravate the current problems and further lead to the proliferation of dialysis and transplantation units which will ultimately lead to escalation of costs returning us to the approach of the early 1970's and late 1960's when it was necessary to deny care to a patient because the funds were not available. It is possible to maintain a medically and cost-effective system preserving access to therapy for all patients with end stage renal disease. The strengthening of the role of the Networks and Health Care Financing Administration in the certification of units and the implementation of regulations discouraging the proliferation of end stage renal disease units (and encouraging cost-effective and medically-effective transplantation) appears to be the least expensive and administratively easiest alternative. With your help and understanding of these interrelationships, access to care for all patients can be maintained.

SUMMARY

(1) The current Medicare end stage renal disease program has save thousands of lives.

(2) Transplantation is currently beyond any question the most cost-effective and medically-effective therapy for suitable end stage renal disease patients.

(3) The proliferation of transplantation and particularly dialysis units represents the major threat to cost and quality control.

(4) The states have not, cannot, and will not administer the end stage renal disease program in a cost-effective fashion.

(5) Ineffective administration of the end stage renal disease program will ultimately lead to the necessity of denying care to some patients because of lack of funds.

(6) Regulations must be changed to correspond with the current medical science of end stage renal disease and with the goal of cost-containment.

(7) The federal government through Health Care Financing Administration or particularly the Networks represent the least expensive and administratively easiest structure for maintaining quality care and cost control of the end stage renal disease program.

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G. James Cerilli, M.D.
Professor of Surgery
Director, Renal Transplant
Program, The Ohio State
University Hospitals
Past President, The American
Society of Transplant Surgeons

STATEMENT OF NANCY SHARP, PRESIDENT, AMERICAN ASSOCIATION OF NEPHROLOGY NURSES AND TECHNICIANS, BETHESDA, MD., ACCOMPANIED BY CARMELLA BOCCHINO, NEWARK, N.J., IMMEDIATE PAST PRESIDENT; JULIANNE MATTIMORE, KATHLEEN SMITH, CHAIRPERSONS OF THE GOVERNMENT RELATIONS COMMITTEE

Ms. SHARP. Thank you, Mr. Chairman.

Senator DURENBERGER. Could you please identify those who have accompanied you.

Ms. SHARP. Yes; I will introduce my colleagues. To my left is Carmella Bocchino, from Newark, N.J. She is the immediate past president of the organization.

To my right is Julianne Mattimore and Kathleen Smith, both cochairperson of the Government Relations Committee.

I also might point out that these two nurses are on the Medical Review Board of the Network 23. Also, I have served a 3-year term on the HSA of Montgomery County, Md. So we are experienced in all aspects of this program.

Our 3,500 member organization consists of professional registered nurses, licensed practical nurses and dialysis technicians who deliver hand-on care to the ESRD patient.

The three areas we would like to address today are the quality of care, the certificate of need process, and patient access.

The issue of quality of care is an important one to us and deserves considerable attention from all. We feel that the certification process, while it has had some positive effects, is woefully inadequate and ineffective in assuring the quality of care.

Some of the difficulties stem from the surveyor's lack of expertise in the ESRD field, leading to troublesome differences in interpretation of the regulations and the lack of continuity between surveys.

We offer three suggestions to correct the situation. One is that ESRD professional experience be a requirement to qualify as an ESRD surveyor. Two, that a surveyor be employed by the medical review board and report simultaneously to the medical review board and the HHS regional office. Three, that in place of the current survey process, perhaps the various professional organizations could voluntarily fund and activate a JCAH-like accreditation system for the dialysis and transplants units.

In addition, AANT is concerned that there will be cuts in the labor portion of the reimbursement rate. This means cutting nurses and technicians from direct care to patients.

While studies on patient-staff ratios have been conducted by the Health Care Financing Administration and others, more attention should be focused in this area. At the very least, our organization feels that it should be required that a professional registered nurse be on duty and present at all times when a dialysis patient is being treated.

We suggest that the quality of care could be enhanced and the cost of the program could be reduced if more responsibility for the chronic therapy given to the ESRD patients were given by experienced ESRD nurses; it would thereby reduce the need for day-today medical supervision.

Physicians would, of course, be consulted for emergencies and new and worsening medical problems, and when changes in the long-term program of the patient care plan are indicated.

In regard to patient access, we feel there are barriers in the area of patient access, that is, in choice of physician, facility, modality, and setting.

The major barriers to patient selection of physician are the lack of open staffing in many areas and the certificate of need process. Barriers to patient selection of facility are the attitudes or experiences of the practicing physician and other health care providers, as well as lack of information disseminated to the patients, and, again, the certificate of need process.

Barriers to patient selection of modality and setting result from physicians' medical judgment and their experience with the various modalities and settings, and the patient's medical condition, and, again, the lack of complete information given to the patient about his treatment options.

We feel strongly that the ESRD program should be flexible enough so that the patients can move from one treatment modality to another without loss of benefits.

Another barrier to patient choice of setting is the lack of funding for dialysis aides. All four of us at this table have experience with the HCFA home dialysis paid aide study, and it is being studied to demonstrate whether making payment available for dialysis aides is an incentive for patients to choose home dialysis.

Patients and family members may not want to or may not be able to assist with the procedure, but the availability of payment for aides gives the patient a real choice about treatment setting.

Some preliminary data from the Orkand Corp. in Silver Spring, Md., currently conducting the evaluation indicates that home dialysis patients have expressed that this is a more normal setting, more convenient, and provides them with better overall care.

Finally, the data collection might remain as a function of a modified network system, or it could be done by small computer firms in the city where it is located.

We have concerns, however, about the possible interruption in the data collection system for even a transitional period if removed from the auspices of the local networks.

Also, should the networks, as we know them today, be eliminated, we strongly encourage that the provisions be made for systems of peer review on the local level.

And as our organization has developed standards of care, this could also be done for each group of providers: physicians, nurses, social workers, et cetera.

Please refer to our written testimony for elaboration on all these aspects. And thank you for this opportunity to express our feelings.

Senator DURENBERGER. How well have the review boards assured that quality care was provided to the ESRD patient?

Ms. SHARP. Let one of those answer that are working on the review board.

Ms. MATTIMORE. Well our network, as you have heard a couple of times this afternoon, has been one of the ones that has been one of the most active throughout the country. And as Bud Bauer mentioned to you, the patient advisory board of that network did come to the medical review board and asked us to look into the complaint or the trouble that they had with lack of disseminating of information as far as the modality and setting were concerned.

We are currently conducting a followup study to the one that he mentioned, and in addition to that, have on a couple of occasions at least investigated patient complaints about grievances that they have had in units.

We are very careful about investigating appropriate complaints, but legitimate complaints about perhaps overcrowding of units and poor staffing have been investigated by the medical review board to the satisfaction of patients and the professional people involved in the network.

Senator DURENBERGER. In your opinion, is it possible that some combination of open physician staffing, elimination of certificate of need, or non-Government accreditation could eliminate the need for medical review agencies? Is that possible while maintaining quality care?

Ms. SHARP. I think we need more than that. Our position is that we are very much in favor of open staffing. We, in this area, have found that a lack of open staffing really limits patient choice. I think that there does need to be specific requirements obviously for admission to open staffing units. But we feel very strongly that the patients need somebody to go to to investigate their problems. And we are very concerned about if the networks go, the medical review board goes, the surveyors go, the patients are going to be left without anybody to go to.

Senator DURENBERGER. Let me ask you about the dialysis technicians. What kind of training does a technician receive, and do you consider it adequate?

Ms. SHARP. Well there is a wide range in the training of the dialysis technician. There are some dialysis technicians who have college degrees and are working in a research capacity, doing research on dialyzers, et cetera.

There are some technicians who are high school graduates who have 6 weeks on-the-job training, which we all agree, including the technicians at the higher level, that that is not enough training for them. They are given then responsibilities beyond their capability and unable to serve the patient in the manner which they should be having.

The midrange technician, where there is perhaps a high school graduate who has had some medical care work, maybe been an X-ray technologist or been an OR technician or something to that effect, and then goes into dialysis, has a much better grasp of the whole system. But even so, the technicians, themselves, we have an ad hoc committee designing a curriculum for these technicians. And even so, even if they come to the unit with some medical care background, we would prefer that there be a 6-month orientation, 6-month combination of theory and clinical practice.

Senator **Durenberger**. It has been suggested during the course of the hearings that hospitals incur higher costs because their dialysis patients have more serious problems and illnesses than patients in free standing facilities. Is that an accurate perception?

Ms. **Bocchino**. I think for the most part it is. Most of the patients that are being kept in hospital centers have some kind of complicating disease or are aged. Unfortunately, I think physician biases do exist as well as nursing biases or institutional biases against home dialysis and transplantation.

Senator **Durenberger**. Do you feel that there are areas in which we are reimbursing physicians where we could be reimbursing RN's?

Ms. **Sharp**. Yes. I think the RN's are not used to their full capacity. The RN comes with an education that is very much able to take care of this chronic diseased patient or the stabilized patient. And I think that they could be given more responsibility at the chronic dialysis unit level, and could follow the patients and implement, based on protocols that are set up jointly with the physicians, and could follow the patients without the day-to-day medical supervision.

There are units that exist now where the physicians do not make a daily visit to the patient, and that is fine. That is appropriate.

Senator **Durenberger**. In other words, there are some groups of providers in which physicians delegate greater responsibility to RN's.

Ms. **Sharp**. Yes.

Senator **Durenberger**. And there are others in which the physicians maintain day-to-day control.

Ms. **Sharp**. Yes.

Senator **Durenberger**. And we are reimbursing——

Ms. **Sharp**. You are reimbursing everybody at the same rate, whether they make daily visits or not. And I am just suggesting that they don't necessarily need to make daily visits either.

Senator **Durenberger**. That is probably an issue we will get into at the next hearing.

I appreciate very much your coming today and the time that you put into that statement. Thank you.

Ms. **Sharp**. Thank you.

[The prepared statement of Nancy Sharp follows:]

Statement of Nancy Sharp, President, the American Association of Nephrology Nurses and Technicians

AANNT TESTIMONY

MR. CHAIRMAN, MEMBERS OF THE COMMITTEE:

It is the pleasure of the American Association of Nephrology Nurses and Technicians to present testimony at these hearings. We come at the request of the Committee and because of our deep and sincere concern about the future of the end-stage renal disease (ESRD) program.

Our 3,500 members--Registered Professional Nurses, Licensed Practical Nurses, and Dialysis Technicians--deliver hands-on care to end-stage renal disease patients, both adult and pediatric, in all areas of nephrology (renal) treatment: conservative management, hemodialysis, peritoneal dialysis, and transplantation. We have three main areas of concern:

1. Quality of care, including certification, the role of Network Medical Review Boards, and staffing;
2. Certificate of Need Process; and
3. Patient Access, including the barriers that restrict patients in their choice of physician, treatment modality, and setting (home or facility).

QUALITY OF CARE

The missing link in the ESRD program appears to be control of the quality of care in dialysis and tranplant units. The other nephrology nurses at this table and I, together, have probably observed between 75 and 80 dialysis and transplant units. At some units, there is a personal, caring concern for the ESRD patients; at others, however, the atmosphere is cold, impersonal, uncaring, and even hostile. These qualities are tangible and can be sensed even by laymen visiting a dialysis unit. Caring and, of course, its absence affect the quality of care delivered to patients.

Certification Process

Under the current Medicare Certification system, a surveyor from the state survey agency visits the dialysis and transplant units once a year. The surveyor checks to see that the units' written policies and procedures, forms, and other required paperwork are in order. The surveyor can be satisfied by reviewing the paperwork. This review, however, does not give the surveyor an accurate picture of the quality of care provided in a unit. For example, one current requirement is that an up-to-date, complete long-term program be developed for each patient. Such a program may be documented on the patient's chart and thus available for the surveyor to check. It does not follow, however, that the patient is aware of his/her program, has participated in its development, or is even aware of the other treatment options available to him. Our association recommends that the current certification process be modified; a review process superior to the present one is desperately needed.

Network Medical Review Boards

The Medical Review Boards of the Networks can fulfill a valuable role in assuring the quality of care provided by dialysis and transplant units. Should the Networks as we know them today be eliminated, it is our hope that there will be provisions for some replacement for the Medical Review Boards.

AANNT strongly recommends a new program of combining the Medical Review Board activities with a more meaningful survey process. We recommend that ESRD professional experience be a requirement to qualify as an ESRD surveyor. ESRD professional experience would enable the surveyor to evaluate whether the spirit of the law, rather than just the letter of the law, is being carried out (proper paperwork present). Use of surveyors with ESRD experience should and could be an effective way to evaluate the quality of care provided by the ESRD program. The surveyor must be able to elicit comments and concerns from both ESRD patients and ESRD staff regarding the quality of care provided in a unit.

We would like to suggest also that the idea of the surveyor's being employed by the Medical Review Board be explored. Under such an arrangement, the surveyor would be responsible for surveying the dialysis and transplant units in a particular network and would report simultaneously to the HHS Regional Offices and to the Medical Review Board. The Board could then monitor and assist the units in implementing corrective actions recommended by the surveyor. Troublesome differences in interpretation of the regulations might then be reduced, and continuity between surveys permitted.

Finally, we suggest that consideration be given to having all the various professional nephrological organizations--whose membership includes physicians, nurses and technicians, social workers, administrators, dieticians, and transplant surgeons--voluntarily fund and activate a JACH-like accreditation system for dialysis and transplant units. Each facility or center could then pay a fee to be surveyed by a team of nephrology professionals. This system would eliminate the need for government funding.

Staffing

At present, Registered Professional Nurses, Licensed Practical Nurses, and Dialysis Technicians deliver direct patient care to the ESRD patient. The nurse manager, along with the medical director and the unit administrator, work together to determine the mix of personnel required to meet the needs of their particular patient population. A national task force of six nephrology nurses (all active AANNT members) and four nephrologists met twice in 1979 under the auspices of the Health Standards and Quality Bureau of the Health Care Financing Administration with the directive to establish acceptable patient/staff ratios. After much heated discussion, the ratios (1:2 for home training, 1:4 for limited care, and 1:5 for self care) were accepted by a majority of the task force. The ratios would guide the surveyor during certification site visits. The surveyor would be able to recognize discrepancies and, in cases where the ratios were higher than those recommended, to ask for clarification. It was our understanding that further guidelines would be issued to assist the surveyor in identifying all the variables in the dialysis patients and units. The variables discussed included age, degree of illness (acuity), location of unit, layout of unit, hospital outpatient vs. free-standing unit, and level of education of the staff.

Network #3 in California is nearing completion of a two-year patient/staff ratio study. The study's main focus has been on determining appropriate level of staffing on the basis of the need classification of the patients. Work in this area is being done by independent units, as well as by networks and professional associations. This is appropriate and should be encouraged. The key individual instrumental in determining the level of staffing needed for each unit is the Registered Professional Nurse responsible for patient care. It is the nurse's responsibility to see that each patient receives safe, competent care throughout the dialysis procedure or pre- and post-transplant.

With the current discussion centering around a reduction in the reimbursement rate to dialysis providers, AANNT is concerned that there will be cuts in the labor portion of that rate. Cutting the labor portion means reducing the number of nurses and technicians serving as direct patient care-givers. Of note by it's absence is any discussion of reducing portion of the physician's fee.

To ensure higher quality of care in dialysis units, this Committee might recommend to the Health Care Financing Administration that, through regulation, the number of Registered Professional Nurses required in each unit be increased. It may come as a surprise to some members of the Committee that the regulations assign responsibility for nursing care in dialysis units to the Registered Professional Nurse but do not require that a Registered Professional Nurse be present at all times when patients are being treated. Our organization feels that this regulation allows dialysis units to function unsafely.

The performance of certain procedures (e.g., venipuncture and medication administration) by Licensed Practical Nurses and Dialysis Technicians is subject to much debate in many states. AANNT is aware of this controversy and has concern as to which member of the health team is responsible for the supervision of these personnel.

Another area of grave concern to our association is the lack of standardized training for all dialysis personnel (Registered Professional Nurses, Licensed Practical Nurses, and Dialysis Technicians). A formal training course that includes extensive clinical supervision should be required of all personnel responsible for patient care.

Perhaps a new approach to caring for the end-stage renal disease patient would assure higher levels of quality of care. We suggest borrowing from the nurse practitioner concept and/or the primary nurse concept. As Registered Professional Nurses, we feel that nurses constitute an extremely valuable asset that the ESRD program as a whole has overlooked. An ESRD-experienced clinical nurse could be responsible for implementing the full patient care plan. Nurses are used for this purpose at Hennepin County Hospital (Minneapolis, Minnesota), which has a program that is very successful in providing high quality care. Chronic dialysis requires chronic nursing care similar to the care patients in nursing homes receive. We recommend that Registered Professional Nurses experienced in ESRD care take responsibility for overseeing the long-term care of the chronic maintenance dialysis patient. This type of nursing management is appropriate and, of course, less expensive than physician management. Some states are now legislating reimbursement for such specialized nurses by third-party coverage.

Physician supervision is essential to ESRD patient care just as it is to nursing home patient care. We would like to propose a structure, however, that would permit nurses to supervise the day-to-day delivery of patient care. Under our proposed structure, physicians would continue as the medical managers of the patient but would not be needed for day-to-day supervision. Even today, in many units physicians do not--nor do they need to--make daily visits to the patients. They are consulted when problems arise, in emergencies, and when changes in the long-term program and patient care plan are indicated.

Briefly, under our plan, the patient and family, and the physician, nurse, social worker, and other staff, would design the patient's long-term program and care plan. The ESRD nurse would then be responsible for it's smooth implementation. The nurse would:

- Assess such problems as secondary complications of ESRD;
- Plan strategies with the patient on the basis of pre-established protocols;
- Call on the physician for consultation as necessary;
- Modify the daily treatment plan within pre-established guidelines;

- Implement and coordinate all aspects of the plan (for example, schedule periodic x-rays, check results, report to the physician, and inform the patient of any further actions); and
- Evaluate and report on patient progress at multidisciplinary patient seminars.

CERTIFICATE OF NEED PROCESS

We are all no doubt aware of the problems encountered in fitting the ESRD program into the Certificate of Need process. Because of my personal experience with this process, I feel that at present this process is unnecessary. Not only is it cumbersome and costly to administer, but it is also extremely time-consuming. By the time approvals are received, costs for completing the projects have escalated, and the type and amount of patient services needed may have changed significantly.

At the local levels the entire process is overridden by politics. The number of stations in an area, the number of patients currently on dialysis, and the potential number of patients entering the program can be manipulated ad infinitum to prove or disprove any position. In fact, "need" should not be the primary consideration in designing a program for delivering patient care. The main issue should really be choice: the patient should be able to choose a physician, a treatment location, choice of treatment modality and setting, and, in the case of facility patients, treatment time.

Because there is a fixed Medicare screen for outpatient dialysis, it may be appropriate to open the program to the marketplace. We feel that doing so would increase competition among providers and lead to enhanced quality of care.

We at this table have all had experience with facilities that had patients on waiting lists. These patients had to dialyze elsewhere and under the care of other physicians until expansions were approved for the facilities they desired. The only alternative for these facilities was to open shifts at inconvenient times for the patients. Implementing this sole alternative increased operational and administrative costs to the providers and could only be done by facilities not already functioning at maximum capacity.

We submit to this Committee that a far more cost-effective alternative would be to allow facilities that are providing good service and have patients on waiting lists to expand their number of stations and maintain hours of operation that are both convenient for the patients and less costly to administer. Facilities that do not provide high quality care or alternative treatment modalities, as well as facilities that function in an uncaring, factory-like manner, would then lose their patients to the more caring providers. And this is how it should be!

PATIENT ACCESS

Barriers to Patient Choice of Physician

The major barriers to patient selection of physician are (1) lack of open physician staffing in privately owned dialysis facilities and (2) the Certificate of Need process which, as previously described, has resulted in a lack of free enterprise in the current system. Independent nephrologists can follow a patient for years for conservative management of chronic renal disease. But once the patient reaches end stage and requires dialytic or transplantation therapy, the physician must transfer the patient to the care of the nephrologists affiliated with the local dialysis center. So much for patient choice!! Until dialysis facilities have open staffing requirements and until the Certificate of Need process is modified or eliminated, patients will continue to be barred from exercising their right to free choice of physician.

Barriers to Patient Choice of Modality/Setting

The barriers restricting patients in their choice of treatment modality/setting (e.g., transplantation, home dialysis) are the physician's medical judgment about and preference for one modality or setting over another and lack of information given to the patient. In reality, the patient should be the primary decisionmaker regarding his treatment and should be able to base his decision on complete and accurate information.

The total ESRD program should be flexible enough to accomodate the patients' moving from one treatment modality or setting to another. In addition, patients should be able to change modality or setting without loss of benefits. Patients are anxious enough about their intitial decision regarding treatment modality and setting. They should not have to fight artificial, provider-erected barriers in making any decisions to change modality and/or setting.

Another barrier to patient choice of setting is the lack of funding for dialysis aides. The four nurses at this table have been involved in a study for the Health Care Financing Administration which will demonstrate whether making payment for dialysis aides available is an incentive for patients to choose home dialysis and whether home dialysis is cost-effective. System Sciences, Inc., of Bethesda, Maryland, the Research Triangle Institute in North Carolina, and The University of Utua were the demonstration contractors. The Orkand Corporation of Silver Spring, Maryland, is conducting the evaluation of the demonstration. Patients and family members may not want or be able to assist with the dialysis procedure in the home. The availability of payment for a dialysis aide gives the patient a real choice of treatment setting. Some preliminary data from The Orkand Corporation's evaluation indicate that home dialysis patients feel that this setting is "more normal," more convenient, and provides better overall care.

We do ~~not advocate~~ the use of monetary incentive to entice providers to encourage other treatment modalities and/or settings. That practice is not in the interest of cost containment, and, more importantly, we have a philosophical problem with the very idea. Providers are professionals in the business of providing medical care to patients in need. They therefore should not need any extra incentives to provide what is best for their patients.

Barriers to Patient Choice of Facility

The main barrier restricting patient choice of dialysis facility is his physician's attitude about particular facilities and, again, the lack of open staffing. Patients should have an opportunity to be referred first to the facility or center that offers the treatment modality he has chosen and that is located nearest his home. The obvious exceptions are when the nearest facility has a very poor level of care and when the patient has made an informed decision to receive treatment elsewhere.

PROGRAM MANAGEMENT

The frequent changes in HHS/HCFA program managers have not instilled much confidence in the program. The change currently proposed adds to the unstable picture. The ESRD program is an identifiable program, with a small number of core providers. It is a relatively easy system to monitor. The program managers will lose the little control they now have if control of the program is further dispersed in the general Medicare system. We need easily identifiable individuals, departments, etc., to contact, sometimes frequently, because of the nature of the program and the constant need to adhere to regulations, reimbursement requirements, etc. The HCFA/ESRD program needs to remain a separate component of HHS, and it needs one identifiable chief.

INTERMEDIARIES AND CARRIERS

We share the concerns of everyone else in the program about the GAO reports uncovering abuses and fraud in the program. The double billing and "phantom patients" billed are surely indicative of negligence on someone's part. Who's to blame? The clerk who punches it in the bill, the person who told the clerk to punch it in, the intermediary who pays the bill, and HCFA, who approved and/or condones it? Patients who have received their bills and seen this double billing are outraged. They know how many dialyses they have had and are aware of the tremendous "rip-off."

DATA COLLECTION AND MEDICAL REVIEW

Data collection, which is vital to the program, might remain as a function of a modified network structure or can be done by small computer firms in each network. In 1980, HCFA finally obtained 100% compliance with the data collection efforts because the forms were funneled through the Network office, and the clerk at the unit who had to fill out the form had someone locally to talk to and quesion about uncertainies. We would like to express great concern about the possible interruption of this process for even a transitional period because data collection is so necessary to so many facets of the ESRD program.

The need for medical review, and the value of it's contributions to monitoring the quality of care provided in an area, have been discussed earlier. The patient needs a local place to send his grievances, where they receive a quick response. It is totally unacceptable to suggest, as it has been, that patients send their grievances to the HHS Regional Offices for action. We recommend that the function of medical review remain at the local level whether in the government-sponsored Network system or in a voluntary provider-sponsored system.

* * * * *

Thank you for this opportunity to respond to these important issues. We are available for questions and consultation at any time.

Senator DURENBERGER. I understand that Dr. Richard Freeman has a 6 o'clock plane. We have agreed to take him ahead of schedule in order that he may catch his plane. Dr. Freeman.

STATEMENT OF DR. RICHARD M. FREEMAN, PROFESSOR OF MEDICINE, UNIVERSITY OF IOWA COLLEGE OF MEDICINE, PRESIDENT, NATIONAL KIDNEY FOUNDATION

Dr. FREEMAN. Thank you. My name is Richard M. Freeman. I am professor of medicine at the University of Iowa College of Medicine, and I am president of the National Kidney Foundation.

The written testimony I will let you read and make only a couple of comments.

I want to say that I agree with Dr. Cerilli regarding our concerns that lack of minimal utilization rates, certificate of need, or some sort of process will lead to the proliferation of dialysis units throughout the country.

I think one tends to think that because of the economic losses related to dialysis of few patients that most hospitals wouldn't be involved in such care. In fact, throughout the country there are many small hospitals that are just dying to have some sort of status, glamor, and believe it or not, even after 20 years, dialysis still has some glamor. They can't get CT scans, they can't do coronary artery bypass surgery, they can't do a lot of things. If they could do dialysis units, dialysis, you could be sure that they would be in almost all hospitals, despite the economic factors involved.

This would not only lead to sequestration away from kidney transplant patients, it would lead to decrease in the home dialysis as well.

In the State of Iowa where I practice, we have had only two dialysis units open since 1973, and actually they opened up in the past year and a half. We trained between 40 and 45 percent of our patients for home hemodialysis, and kidney transplantation is No. 1 in the Nation per capita in terms of the number of transplants that are being done. And I am sure that the ability to control the growth of dialysis units is largely responsible for that particular data.

The other comment I would like to make has to do with networks. We mildly favor the continuation of networks for many of the factors that have already been mentioned today.

You should keep in mind, however, that networks cost more than the $5 or $10 million that are actually paid for their sustenance. For example, each time a network does a study, the data that is produced as produced by facilities, costs money as well. So that we feel that if networks are to be continued, they need to be controlled so that they do not grow endlessly, and that the objectives of the networks be kept in mind.

Thank you very much.

Senator **Durenberger**. Thank you.

On the last point, I take it you agree with some of the other witnesses that the networks are better than nothing at all, but that we need to give them greater focus.

Dr. **Freeman**. They are clearly getting better now. It has taken them a long time to get moving, and in the past year and a half I think in many areas they have been successful. But there is wide variation in terms of that success.

Senator **Durenberger**. Is it your opinion that getting patients to dialyze at home is a matter of restricting access to in-center dialysis?

Dr. **Freeman**. That is probably one of the ways of doing it. In a State such as Iowa, I am convinced that it is better to dialyze at home than to drive 60 miles on a snowy day in January. So I have something going. On the other hand, I suspect if there were dialysis units every 30 miles throughout Iowa, there wouldn't be many on home dialysis.

Few people want to take care of themselves, initially. Once they have learned to take care of themselves, they seldom want to stop. But it is not something one automatically gravitates toward.

Senator **Durenberger**. What has your experience been with respect to the degree to which a physician's decision on alternatives is influenced by the existence of a fairly substantial investment in dialyzing equipment in a hospital or other center which that physician utilizes?

Dr. **Freeman**. It has some influence, just like I like to keep my home dialysis training unit full. You don't want to have nurses and technicians that are not working. So it does have an impact on that, maybe a subconscious impact. But once you have a facility, you want to utilize it fully, regardless of what kind of facility it is.

Senator **Durenberger**. All right. Thank you very much.

[The prepared statement of Richard M. Freeman, M.D., follows:]

TESTIMONY OF RICHARD M. FREEMAN, M.D., PRESIDENT, NATIONAL KIDNEY FOUNDATION

My name is Richard M. Freeman, Professor of Medicine at the University of Iowa College of Medicine, and President of the National Kidney Foundation. I speak on behalf of the lay and professional volunteer membership of this organization, which is the leading voluntary health organization dedicated to the needs of patients with kidney and urologic diseases.

I want to thank you once again for a federal program which is responsible for the lives of at least 50,000 Americans. In particular, racial minorities, women, the elderly as well as the very young now receive medical treatment without discrimination. This was not always true 10 years ago. It is important to keep this success in mind as we begin a criticism of the ESRD program.

My comments will be directed to four areas:

1) Utilization and access
2) Program management
3) Quality of care, and
4) Program data and research.

Utilization and Access

We believe that the existing **MINIMAL UTILIZATION RATES** are appropriate. They seem to be providing a healthy balance between forced overutilization if the minimum utilization rates were increased, and unnecessary proliferation of facilities, particularly small facilities, if minimal utilization rates were decreased. We are concerned that the lack of minimum utilization rates will lead to many unnecessary dialysis facilities. Transplantation surgeons in particular are concerned that a proliferation of small dialysis units would lead to sequestration of patients away from kidney transplantation. An adverse effect on the home dialysis population is equally likely.

Some constraint and control, both with regard to facility planning and quality control, are felt necessary. The **CERTIFICATE OF NEED** per se may or may not be the mechanism for achieving this. The network system might be equally effective. In any event, a group with specific ESRD expertise and knowledge of regional needs is highly desirable in order to control the cost of the program as well as the quality of care.

ACCESS TO HOME DIALYSIS has been restricted by inadequacies in legislated or regulated methods of payment, such as the inclusion of paid aids under the target rate reimbursement program (a dismal failure) and the ill-defined methods of reimbursement for continuous ambulatory peritoneal dialysis. Inconsistencies in payments between different intermediaries, few patient incentives, and failure of payment methods for the support systems and personnel necessary to keep trained patients at home are also barriers to home dialysis success.

In some but not all geographical regions an important **BARRIER TO KIDNEY TRANSPLANTATION** has been the lack of adequate cadaveric organs. This may be in part due to lack of a uniform brain death law in some states. There has furthermore been a variable success rate in cadaveric kidney transplantation. The average age of patients in many dialysis units is now approaching 55 years, and it is not therefore surprising that many concomitant medical problems of this patient population preclude successful kidney transplantation. Finally, there are differing philosophies and attitudes in many physicians concerning transplantation vs the various forms of dialysis therapy now available.

The United States' experience with home dialysis, center dialysis and kidney transplantation is unknown with regard to morbidity and mortality. Certain published series compare favorably with data published from the European Dialysis and Transplant Association. We have no national data, however, for a true comparison with western European countries.

Program Management

We feel strongly that there should be a **FOCAL POINT IN THE HHS FOR MANAGEMENT IN THE END STAGE RENAL DISEASE PROGRAM**. The turnover in personnel in this management group must be minimized. Furthermore, those assigned to this area should have expertise in the field. Prior reorganizations have resulted in confusion, inconsistency and inefficiency in management. There is no reason to believe that this will not again occur with the current reorganization. The ESRD program should be afforded a high priority in the HHS.

PERFORMANCE BY THE INTERMEDIARIES AND CARRIERS has been inconsistent from region to region with little coordination nationally. We are unaware of any assessment of performance or by what mechanisms performance might have been assessed. A single national intermediary with a knowledgeable medical advisory board might solve many of the problems we have encountered.

We have found the **NETWORK PERFORMANCE** to be quite variable, some having performed valuable roles in identifying problem areas and insuring quality of care, in limiting proliferation of costly and unnecessary facilities, and in accruing the only accurate ESRD data available for a region. Other networks have been less effective or minimally effective in these areas. On balance we believe the networks should be maintained since they represent a valuable focus of ESRD expertise not available in other review groups. They are constituted in such a way that they are cognizant of and sensitive to local-regional conditions yet do not represent a single interest group. They seem uniquely suited to achieve the most realistic facility planning, quality care review and data collection in each region. We should recognize, however, that the cost of the network system is certainly more than the 5 to 10 million dollars paid by the federal government for their actual maintenance. Each study performed by the network requires time and effort on the part of the facility to obtain the appropriate data. As long as each study is of distinct value, this additional cost is probably acceptable. There is a tendency for federal bureaucracies to increase in size and the networks have been no exception to this generalization. If the objectives of the networks are well-defined and the growth of the networks is controlled, we believe their continuation is in the best interest of the ESRD program.

Quality of Care

There has been duplication of effort costly both to surveying agencies and the facilities being surveyed in the **ON-SITE SURVEY PROCESSESS.** At different times facilities are subject to survey from federal agencies, state agencies, the network and the Joint Commission on Accreditation of Hospitals. Ideally this would be reduced to a single on-site annual survey (probably done by the network) which would accomplish the most meaningful peer review. The report of this single body should be accepted by all other interested groups.

In general, the **MONITORING OF QUALITY OF CARE** in the ESRD Program has been more "process" than "outcome" oriented. For example, one recent audit was an attempt to determine whether or not patients were being informed about the possibility of kidney transplantation. It would seem to be unnecessary for such a "process" audit to be performed in those institutions where kidney transplantation is being done at the highest per capita rate in the country. Such process audits might be appropriate in those dialysis facilities where dialysis patients are seldom transplanted. The same criticism can be directed toward process audits on home hemodialysis. Where the percentage of patients on home hemodialysis is high, patients are clearly being informed of this possibility whether or not a written statement appears in the patient's chart. Unfortunately, we believe there are a variety of ways in which process audits can be circumvented. The only certain way to insure that all patients with end stage renal disease are informed about kidney transplantation and home dialysis is to insist that such patients be evaluated in centers which have these capabilities. We are not totally certain that even this maneuver would totally solve this problem.

We believe that the **STAFF QUALIFICATIONS** related to quality care are appropriately set forth as minimum standards in current ESRD regulations. These standards should be maintained. We believe that quality of care should be monitored by outcome audits as mentioned above and not by mandating any specific staffing levels.

Program Data and Research

The **MEDICAL INFORMATION SYSTEM** has failed to provide any but the simplest demographic data concerning the ESRD Program. The lack of the most superficial medical information such as treatment modality survival data is a source of considerable embarrassment to the medical community.

We believe, furthermore, that adequate sanctions exist in the current ESRD regulations to assure adequate data collection. Since primary data collection on the federal level has failed and since data collected at the network level has been successful in several networks, we urge that networks be staffed and funded to collect analyzed data in a uniform manner with prompt reports of such data back to the facilities.

Thank you sincerely for giving the National Kidney Foundation the opportunity to prepare testimony for these hearings.

Senator DURENBERGER. Our next panel consists of Howard Bochnek, executive director of the ESRD Network 25, from New York, N.Y.; Dr. Robert Gutman, who is from the National Forum of ESRD Networks, Durham, N.C.; Patricia J. Lyons, M.D., chairperson, and Ronald Wrona, Ph. D., executive director of Network No. 24, King of Prussia, Pa.; and William Pfaff, M.D., chairman of the medical review board of the Florida ESRD Network, director of the transplantation program, Shands Teaching Hospital, Gainesville, Fla.

Mr. BOCHNEK. We have chosen a priority, other than alphabetic, and more in keeping with the significance of the providers of care. The physicians will speak first.

Senator DURENBERGER. All right.

Dr. GUTMAN. That is a pejorative that I wish I hadn't been saddled with.

STATEMENT OF ROBERT GUTMAN, M.D., NATIONAL FORUM OF ESRD NETWORKS, DURHAM, N.C.

Dr. GUTMAN. I am Robert Gutman of Duke University where I am the director of the dialysis unit, and I represent the physicians who work within the network system.

Perhaps one of the reasons I am here is that I authored an article which was published in the New England Journal of Medicine concerning the status of patients on hemodialysis. And one of the things we did was to put forward that data collection as a model of a system which might be useful.

I will try to summarize the written statement which I believe is in your possession.

Several closely related issues command our attention today. They are (1) concerns about patient morbidity or the degree of illness, an issue which has finally begun to receive the same interest as simple mortality rates, and is, as someone else mentioned, the other side of the so-called rehabilitation issue.

Second, the planning for services with due regard for the cost involved and with due regard for the subsets of patients which are involved.

Third, the problem of accumulation of useful information.

We agree with Dr. Davis' comments concerning the problems with the present data.

And, finally, the role of the networks in these areas.

All, I think including Dr. Davis, have recognized the recurrent theme central to these issues which is inextricably linked to the question of the sources and the value of data. We in medicine have our own jargon. By "data," I mean, of course, useful and valid information.

Solid, useful and continuously renewing data are required by both Federal administrators and health care providers in this and any other system. The single set of data to which Dr. Davis referred earlier will be available in 2 years, as she said, and it will be useful for the time it was collected. But it will be less useful as new modalities of treatments are added; hence, the need for continuously available information.

The reports received by the Health Care Finance Administration, represented by the MIS directly from the field, is necessary information, but is insufficient in many respects. Such data are inevitably filed in a perfunctory fashion.

Recognizing this, HCFA asked for very little. The resulting tabulations are often meager and flawed by the lack of validation procedures. They do not stimulate a sense of participation from the providers of these data.

We have learned in many cases that unless there is feedback, and unless the feedback contains useful and interesting information, the quality of data on the next go-around may be poor. Where the size of the group working together to collect data is of manageable proportion, the amount of information which can be reliably gathered is greater. This is largely because the participants learn in a short enough time what they want to know, and are, therefore, willing to continue the process.

Accordingly, the value of the data grows and the sense of participation grows.

The usefulness of this kind of collegiality was exemplified in the article I just mentioned and which was quoted in the lay press.

We presented a fairly solid, though preliminary, set of information concerning the degree of rehabilitation achieved by several subsets of dialysis patients. It was published because HCFA did not have such data. Similarly, the indirectly Federal-funded SEOPF [Southeastern Organ Procurement Foundation] was able to recently identify which subset of patients do well after a transplant and which do not. This is valuable information whether one is concerned about cost, rehabilitation, or planning.

The networks possess the same advantage of size. Most are large enough to have a meaningful experience and small enough to have direct impact. The networks which have emphasized data collection recently have been strong and useful members of the team and have been most helpful to MIS.

Networks provide a forum which emphasize the shared responsibility of patients, nurses, social workers, and physicians. The major tool for such a group is information.

When this information has been returned to the facilities, it has encouraged improvements in medical care, and frequency of contact and in the processing of grievances. When the information is shared with State certification agencies, it has help in the planning and distribution of facilities. When it was passed to MIS, it improved their reporting.

The networks have already begun to be providers of good data, even before they were given a clear mandate. They are the right size for the job and their councils are functioning. Their existence is important to patients because that is where they can be heard, to health care providers because the pool data may be useful in future planning, and to MIS because they are able to improve the quality of their data.

Thank you very much.

Senator **Durenberger**. Thank you. Are we sticking with the doctors now?

Dr. **Gutman**. Yes, sir.

[The prepared statement of Robert A. Gutman, M.D., follows:]

TESTIMONY BEFORE SENATE FINANCE COMMITTEE
OVERSIGHT HEARINGS
SEPTEMBER 28, 1981

Robert A. Gutman, M.D. representing Forum of ESRD Network Coordinating Council Directors.

INTRODUCTION

Ladies and gentlemen, providers and administrators of health care programs, specificially ESRD services, agree that information, carefully collected, collated and displayed has been the best guide to assess and influence quality of care. Physicans and other health care providers are willing to submit data to improve health care and control costs as evidenced by the following:

> An article I authored which appeared in the New England Journal of Medicine contained a set of outcome data in which we reported mainly on the physical activity and job rehabilitation of various groups of patients being treated by maintenance dialysis. Our study was carried out through volunteer efforts. No financial support was available which serves to emphasize physicians' interest in the process of information sharing and their willingess to participate in meaningful efforts to collect and analyze data. Information generated by our study represented the kind of data needed to better assess outcomes of ESRD services. One of its limitations was that the study was based on a single point in time. Ongoing data are needed to provide a useful mechanism to review quality of care.
>
> One closely related program demonstrates a similar willingness of health care providers to participate in information sharing activities. The Southeastern Organ Procurement Foundation (SEOPF), which is indirectly funded by the Federal Government, has been quite successful in collecting, displaying and sharing clinical and outcome information (from which cost data could be derived). This continuing collegial sharing of information has contributed to the improvement of the care given to transplant patients in all the affiliated transplant facilities.

Networks have initiated ongoing data collection activities to monitor and assess quality of care, distribution and utilization of services and provide ongoing educational information to the providers and administrators of ESRD services. I represent the physicians who have been active in the Network Coordinating Council system because of our recognition of the inherent values of sharing information among groups large enough to have a meaningful experience and small enough to have a direct impact on patient care and related policies. We are concerned about fair and even distribution of medical services for patients with advanced kidney failure and we are concerned that this care be provided at a reasonable cost. We recognize the value of useful information in trying to reach these goals.

The networks were created in the same spirit that led to the creation of the PSRO's anticipating that local medical review activities would arise from their councils to assure that care be of high quality and reasonable cost. Initial attempts of Medical Review Boards (MRB) to model themselves after PSROs have met with mixed success. Inherent differences between retrospecitve review of hospital records of people with relatively easily treated short term illness as compared to prospective review of the care of people with long term illnesses were not recognized at first. PSRO'S themselves, except in a few cases, were unable to initiate effective review of long term care programs and have modified the use of medical care evaluation studies considerably. Instead, we have found that profile analysis (collection and display of data) is more useful in monitoring quality assurance and identification of needed indepth studies than relying completely on medical care evaluation studies.

Networks are self-managing, independent structures, operating within federal guidelines and policies. The network structure requires all categories of ESRD professionals (physicians, nurses, social workers, dietitians, technicians and administrators) and patients to interact in the performance of network activities. Networks provide a unique expertise not possessed by any other existing agency or organization enabling them to evaluate local resources, program needs and patterns of medical practice when planning for and ensuring the delivery of nigh quality ESRD services. The interaction of patients and professionals from the various categories ensures a comprehensive approach to those issues and problems which cannot be resolved by individual professional groups or by facilities alone. In addition, the network mechanism allows all members of the ESRD community to review, implement and monitor changes in the ESRD program in collaboration with the Federal Government.

Networks have made considerable progress in carrying out the mandated functions of PL 95-292 through a variety of activities that may be categorized as follows:

1. Quality assurance and long term program monitoring
2. Review and monitoring of utilization and distribution of ESRD services and resources
3. Encouragement of home training, transplantation and rehabilitation
4. Patient participation
5. Data collection activities

By way of responding to some of the issues identified for discussion by this committee, each of these activities will be reviewed by answering the following questions:

1. What is required to carry out these activities?
2. What data are necessary?
3. How effectively have networks performed in these areas in the past and how might they participate in the future?

Due to considerable interest in the Medical Information System (MIS) and data needs at all levels of the ESRD program, including cost/reimbursement information and the relationship between networks and the MIS, these issues will be discussed in the conclusion of this statement.

QUALITY ASSURANCE MONITORING

The monitoring and assurance of quality will function best when it is based on the long standing interest of American medicine in information. By reviewing and analyzing valid data, many of us alter our policies and, in addition, most will respond favorably to peer pressure. An ongoing local mechanism is needed enabling ESRD professionals to review meaningful information and carry out relevant studies as indicated.

For information on the quality of ESRD care to be useful, it should be reasonably complete. The more complete it is the more it resembles clinical research which has historically provided the basis for identification of needed changes in clinical practice. The data should be available on an ongoing basis as clinical practice in ESRD is changing continuously. Data should measure the degree of sickness of patients as well as their death/survival rates and should include enough information about patients and related changes in status to illustrate the effect of outcomes of various therapies . Local data from facilities is essential to identify and implement needed changes in patient care. The MIS provides a data base against which local data can be compared.

Regarding clinical research, the informational needs of the federal administration and of health care providers is essentially the same except that health care providers generally need somewhat greater detail than administrators making "clinical research" data more expensive and time consuming to obtain. We do not believe, though we might regret, that the networks or MIS can carry out clinical research routinely; however the network structure provides the basis for enhanced data collection efforts. For example, a network or group of networks with a specific interest could apply for grants or make budget requests to carry out specific research oriented studies if they chose.

Nearly all networks have reviewed mortality data and responded to queries by PSRO's and survey agencies to evaluate circumstances surrounding questionable ESRD patient care or deaths. Networks and some individual facilities have organized seminars to review data and identify ways to reduce mortality. Some of the corrective actions resulting from the dissemination of accurate mortality information include:

- Alterations of treatment selections; e.g., extremely high mortality among home peritoneal dialysis patients resulted in decreased emphasis on this treatment modality.

- Modifications in frequency of patient/physician interaction.

- Medical Review Board onsite visits to facilities with high mortality rates facilitated identification and resolution of specific problems.

Specifically,

- Several networks can demonstrate a decrease in overall patient mortality over a three-year period.

- Individual facilities have decreased mortality by as much as 50%.

Testimony--Robert A. Gutman, M.D.

The network Medical Review Boards have established standards of care in order to improve the morbidity and quality of life of ESRD patients. Examples of studies or investigations carried out by the networks which have had impact on patient care include:

- Monitoring of long term programs to include adherence to agreed upon standards and criteria for patient selection.
- Nutritional assessment procedures were modified based on a review of the adequacy of nutritional services for ESRD patients.
- Standards for staff/patient ratios were established as a result of a survey of current ratios for physicians, nurses, social workers and dietitians.
- Studies of osteodystrophy diagnostic and treatment procedures have led to changes in diagnostic and treatment procedures.
- Review of mortality data as previously described.
- Review of transplant graft survival data have brought transplant surgeons together to identify needed changes in the management of patients who have received a transplant.
- Tracking hepatitis incidence and prevalence and reviewing procedures for hepatitis control, have produced decreases in incidence and prevalence of hepatitis.
- A study of water treatment procedures resulted in increased frequency of water testing.
- Some facilities added safety equipment to dialysis machines based on a study of safety equipment.

Other studies, the significance of which will be determined through follow-up activities, include:

- Incidence of bacteremia in dialysis patients.
- Management of anemia in dialysis patients.
- Incidence of access procedures (modifications in dialysis access) was reviewed.
- The review of patient outcomes based on rehabilitation status.
- Backup use of hospitals and centers by facility, home and transplant patients has been analyzed.
- Incidence of hypertension among dialysis patients.
- The awareness of ongoing review activities has provided a "peer conscience" to reinforce quality of care in ESRD facilities.

Testimony--Robert A. Gutman, M.D.

DISTRIBUTION AND UTILIZATION OF ESRD RESOURCES AND SERVICES

Currently the distribution of services is determined by utilization of existing services and by the need for additional services as identified by networks, health systems agencies (HSA's), state cerificate of need offices (CON) and the Health Standards and Quality Bureau (HSQB) regional offices. Both administrative and legislative changes propose to minimize the role of networks, HSA's and the ten (10) regional offices shifting responsibility to the central office of HSQB and CON agencies where they exist. Efforts to encourage the addition of new ESRD providers, which is bound to occur if all review activities are curtailed, may be counterproductive as reimbursement rates are reduced and emphasis on transplantation and home dialysis are increased. States with strong CON legislation will continue to regulate the addition or expansion of services, but other states will look to the federal government for guidance in this area.

For CON agencies and HSQB to continue efforts to identify (1) areas of significantly high or low incidence, as influenced by trends among population groups (e.g., increased incidence of ESRD among the elderly) and (2) inequities in distribution of services (e.g., patients travelling long distances) ongoing valid data must be available. Patient and facility specific data are required to determine the overall incidence and prevalence of ESRD as well as the specific distribution of patients by county, facility, race, sex, and age.

To date networks have been the only agency, with the exception of a few state ESRD registries, capable of providing timely, accurate data suitable to meet the needs of those individuals and groups ultimately responsible for approving the addition of ESRD services. Networks have established close working relationships with HSA's and CON agencies supported by Memoranda of Understanding providing the expertise necessary to effectively evaluate and plan for needed ESRD services. Some of the activities undertaken by networks include:

- sharing of data on a regular basis with all agencies interested in or responsible for planning ESRD services

- establishment of utilization criteria which encourage the addition of evening shifts in some areas, thus accomodating patients who are employed

- adjusting for altered utilization of home training and isolation stations, encouraging the availability of both services in the local community

- made on-site visitation of some facilities prior to making recommendations on their applications

- mediated conflicts between potential competing applicants during the review process

- educational programs for ESRD professionals when new services are added to an area

- support for single shifts in areas of sparce population when a single shift is more cost effective than two shifts per day
- development of plans for needed ESRD services in conjunction with HSA's and state agencies
- development of specific criteria to provide guidance in the review of applications for the addition or expansion of services
- provide technical assistance to potential applicants with regard to appropriateness or in the preparation of ESRD related applications
- maintenance of current directories which include utilization data as as well as information to assist patients wishing to travel, to facilitate interfacility referrals for specialized services and to guide local, state and national agencies seeking information about available services.

Testimony--Robert A. Gutman, M.D.

HOME TRAINING, TRANSPLANTATION AND REHABILITATION

Public Law 95-292 provides important incentives for modalities which enhance the potential for rehabilitation and improve the cost-effectiveness for the ESRD program. Home training and transplantation have been identified as the modalities most likely to meet those requirements. In addition to the release of regulations introducing incentives for home training and proposed regulations to minimize reimbursement for center dialysis, facilities and networks have worked together to establish goals for home training and transplantation. Each provider must continue to be aware of the need to focus on cost savings and rehabilitation as essential to the continuation of the services to ESRD patients.

In order to monitor the impact of regulations in changing the delivery of ESRD services and the overall costs of the program, accurate, timely data are essential. While facilities are required to submit data, the accuracy of that data has been questionable until the networks were asked to assist in assuring validity and completeness of the patient data submitted to the MIS.

Networks have participated in efforts to encourage, consistent with sound medical practice, the optimal use of home dialysis and transplantation and improvement in the rehabilitation status of ESRD patients by:

- establishing goals and monitoring attainment of those goals both at the network and facility level

- developing standards for selection for home training and transplantation and monitoring long term programs for compliance with those standards

- encouraging communication through sharing of data and educational programs for ESRD staff and other agencies interested in ESRD services, i.e., HSAs, PSROs and CON staff

- establishing communication with vocational rehabilitation services and sharing information with patients about available resources

Networks have established numerical goals and monitored progress by reviewing data as to:

- number and percentage of new patients entering and completing home training and receiving a transplant

- number and percentage of patients dialyzing at home and, in some networks, living with a transplant

- utilization of training stations and transplant centers

- Number and percentage of patients returning to facility dialysis either from the home setting or as a result of graft failure

Networks have established standards and criteria for the evaluation, selection, education and documentation of patient potential for home dialysis or transplantation with specific consideration, in some networks, for the needs of children and pediatric facilities.

Testimony--Robert A. Gutman, M.D.

Through educational programs, frequently based of the sharing of data, and peer pressure, networks have altered existing treatment patterns.

- Data on morbidity and mortality have encouraged transplant surgeons to initiate discussionn among themselves regarding changes needed to improve the results of transplant.
- Mortality data of intermittent peritoneal dialysis led some providers to limit the use of this modality.
- Facilities have initiated more comprehensive orientation/education programs for patients entering dialysis.
- Networks have sponsored patient care planning workshops to enhance skills in increasing patient independence and improving rehabilitation.
- Networks, facilities and individual providers have participated in educational programs directed toward understanding the legal, moral and practical aspects of brain death and organ procurement.

Networks have emphasized the importance of communication among various health disciplines within and outside the renal community leading to the establishment of organ procurement agencies, a new transplant society, major changes in local and state health planning documents and modifications in reimbursement policies.

Testimony--Robert A. Gutman, M.D.

PATIENT PARTICIPATION

P.L. 95-292 encourages patient involvement and representation in the ESRD program. While patients can communicate with ESRD program staff and with the staff at their individual facilities, a local forum provides a more appropriate mechanism for their concerns and interests to be expressed. Through local involvement patients are more likely to understand the ESRD system and thus can identify relevant needs for improvements.

Physicians have found that network data were helpful in communicating with patients, on an appropriate level, regarding outcomes of various modalities potentially available. Ultimately, a more complete data system may become a valuable tool to assist patients and physicians in selecting appropriate modalities of care.

Network accomplishments in the area of patient involvement include:

- representation on network coordinating council and the executive committees.
- patient advisory groups assist in the determination of policy on patient related issues, review potential patient oriented materials, comment on standards for provision of ESRD care and develop materials to meet previously unmet patient needs for information.
- opinion surveys providing information about the level of satisfaction of patients with their treatment and their attitudes toward the health care delivery system.
- newsletters and telephone lines encourage communication between patients and providers.
- patient involvement in advocating for appropriate state and national legislation which may effect ESRD services, i.e., brain death legislation, nurse practice acts, reimbursement policies, and the overall ESRD law.
- establishment and review of grievance procedures, rights and responsibilities.
- formulation of patient support groups.

Testimony--Robert A. Gutman, M.D.

NEEDS FOR DATA

The same regulations and later revisions of the law which established the networks created the Medical Information System (MIS). The data generated by this system was to provide the basis for the Annual Report to Congress which includes data on the number of patients by setting, utilization rates and cost of ESRD services. The expectations of nearly every group interested in this system have not been met until recently when the networks became involved in providing data to the MIS. Since local groups working together have a need, the ability and the interest in data collection and analysis, the improvements in the system by transferring major responsibilities to the networks were not surprising. The positive results of networks' role in collecting and validating data on behalf of the MIS are evident. The MIS is now able to produce accurate patient counts by setting and local Medical Review Boards and Planning Committees can initiate meaningful quality assurance and utilization related data.

Can we manage without data? In a word, No. Each section of this report explains how data have been and must continue to be used to improve patient care, monitor utilization and outcomes of services and, ultimately, to control the costs of the program by identifying those modalities that are cost effective and provide positive outcomes. The need for a strong base for patient related information has now been established. Individual physicans, facilities, networks and the federal administration can build on that base of information in a variety of ways. Yet to be established is a clear mechanism to collect, analyze and compare cost data. Networks have previously expressed an interest in such data but have given priority to patient oriented data.

SUMMARY

The strength of the successful networks lies in their collegiality and managability of size. To the degree that they grow larger, should network consolidation be seriously considered, they are likely to share the problems of the larger, impersonal MIS sytem.

In summary the networks, in many areas, have grown into a system of collegial interchange of useful information. They are able to collect data because the data are relevant and are reviewed and analyzed locally. The process of collecting and displaying information within the networks has resulted in improved policies and practices at numerous facilities. This process, based on sharing of information, peer pressure and education, more than the more formal, less personal PSRO style of review, can improve quality and ultimately minimize increases in costs of the ESRD Program.

SUPPLEMENT TO TESTIMONY
Presented by Robert A. Gutman, M.D.
OVERSIGHT COMMITTEE HEARINGS ON ESRD
SENATE FINANCE COMMITTEE
September 28, 1981

The following is an addendum to the testimony presented at the Senate Finance Committee Oversight Hearings on ESRD by Dr. Robert A. Gutman, M.D., who participated on the panel for Network Coordinating Councils.

The impression was given by the Director of the Health Care Financing Administration (HCFA) that networks had failed to meet their responsibilities as defined in federal regulations. The attached document summarizes many of the accomplishments of networks in the areas of appropriateness of care, morbidity and mortality studies; patient and program support activities; and data collection. The first column summarizes basic information about each network to include the area served, the number of approved dialysis facilities and stations and transplant centers and the number of dialysis patients being served. This information is included to emphasize the wide variations among networks which may have had impact on the number or extent of activities undertaken. In addition, you should be aware that networks are operating with limited staff support. Most networks have two professionals and none have more than three professional staff members. When compared to PSROs, the networks are serving a larger geographic area and they are coordinating activities in a variety of areas with physicians and other professionals who have not previously worked together.

Network accomplishments have been spelled out each year in Network Annual Reports submitted to the ESRD program office. Unfortunately, however, the information in those reports has not been used in the preparation of the Annual ESRD Reports to Congress. The 1980 Report was completed before Network Annual Reports were received; and we further understand that the 1980 Report to Congress has yet to be submitted.

Initially, networks expected to have access to the data required to meet their responsibilities through the Medical Information System (MIS); however, that system has failed to meet our expectations. Due to the sincere interest of network staff and professional volunteers in having valid data upon which to base medical and other related decisions, many networks developed their own individual patient data collection systems. It was, in fact, the access to data at the network level that led to identification of specific problems in the MIS data. As a result networks were asked to assume full responsibility for collection, validation and submission of all non-reimbursement MIS forms effective January 1, 1981, in addition to the semi-annual Facility Survey and Patient Census for which they had been responsible since 1978. To support their reporting responsibilities, networks were permitted to establish access to computerized data processing. In the final column of the attached summary the status of each network's data collection system is briefly described.

Although not specifically identified in the attached network summary, the effort required by network staff to meet MIS reporting responsibilities must be acknowledged. Each of the forms identified below are received, logged, reviewed, revised and, in some instances, actually completed by network staff before they are sent to the MIS staff in Baltimore.

1) FACILITY SURVEY - An aggregation of the activities occuring at each facility during a six-month period is completed semi-annually. Thirteen networks are completing these forms on behalf of the facilities in their networks utilizing the data available in the network office. (1,033 facilities reporting twice a year = 2,066 forms)

2) PATIENT CENSUS- A Census was completed initially in 1978 and a second Census was validated in 1981. Networks have been advised that they will be asked to review the complete Census twice more during 1982. Facilities and network staff have worked together to accomplish the tedious task of validating the status and demographic data on each patient listed on the census for each facility. Some networks have identified hundreds of patients inappropriately identified as ESRD Medicare recipients. An even greater number required corrections in specific data entries. (Data on approximately 55,000 patients individually validated, in addition to several thousand inappropriately listed)

3) ESRD PATIENT HISTORY FORM - These forms are submitted for each new patient entering the ESRD system. (Approximately 20,000 new patients during a 12-month period)

4) ESRD TRANSPLANT TISSUE TYPING INFORMATION - These forms are submitted by transplant centers with each transplant performed. (Nearly

5,000 transplants during a 12-month period)

5) ESRD DEATH NOTIFICATION FORM - These forms are submitted within two weeks after the death of either a dialysis or transplant patient. (Approximate 11,000 deaths during a 12-month period)

More than 38,000 individual forms plus the Patient Census, requiring validation of nearly 55,000 individual patient records, are handled by 32 networks. Participation in these activities is a required network function; and, especially when network staff are assuming the major responsibility for completing the census validation and/or the facility survey on behalf of the facilities, the efforts of approximately a half-time person are required.

Another activity not clearly spelled out in the attached summary is that of planning for needed ESRD services and the review of applications to expand existing services or establish new ESRD facilities. All networks have assumed a strong role in working with the planning and review agencies within their area. Most serve as the sole source of prevalence, incidence, mortality and referral data for planning activities and provide initial estimates of projected need for future services to planning agencies including the Health Standards and Quality Bureau, the agency ultimately responsible for providing certification to ESRD facilities. Due to changes in priorities both within the networks and the current administration, network planning functions are being modified; however, previous efforts in planning have laid the ground work for the distribution of ESRD services. Networks will continue to respond to requests to review competing proposals or applications to establish new programs. As was pointed out in the testimony at the hearing, complete deregulation of facility certification could destroy present efforts to encourage home training and transplantation. Most networks could provide data to show that newly established facilities rarely initiate home training activities until they have been operational for at least a year or until they are at 80% or greater capacity.

We cannot conclude this statement without formally acknowledging the cooperative support we have received from the ESRD program staff this past year. Network staff, physicians, other ESRD professionals and patients have worked with ESRD staff through participation on numerous task forces that have been established to assess networks, improve data collection and management, identify rehabilitation issues, develop goals and objectives and arrange national workshops on program coordination and profile analysis. At last we have a clear statement of expectations in terms of uniform, mutually agreed upon goals and objectives and a cooperative data system to facilitate attainment of those goals. We look forward to the opportunity to continue to provide a forum for physicians, other professionals, patients and staff to work together to improve the care of ESRD patients.

SUMMARY OF NETWORK ACTIVITIES

NETWORK INFORMATION KEY:	APPROPRIATENESS OF CARE STUDIES (Through 1980)	MORTALITY/MORBIDITY STUDIES (Through 1980)	PATIENT/PROGRAM SUPPORT ACTIVITIES (Through 1980)	DATA COLLECTION ACTIVITIES (As of August, 1981)
Network number and location (city and state) Territory (*) indicates part of state Number of dialysis facilities, number of stations 7/1/81 Number of transplant centers 7/1/81 Number of dialysis patients 1/1/81	Activities given the general title of "Long Term Program" and "Appropriateness of Care", by definition in the regulations, include: Admission to the ESRD Program, Selection for home or self-care training, Referral for Transplantation, Process and documentation of Long Term Programs and Patient Care Plans by a team (physicians, nurses, social workers and dietitians.) All of these activities support and guide the care of ESRD patients.	A broad range of activities illustrate network activities as they relate to patient outcomes or the actual process of providing care. While all networks have access to general mortality data, some have developed very specific profiles. Outcome or morbidity studies are usually based on hospitalizations, vascular access revisions, incidence of hepatitis or the management of a specific disease entity. Some networks have studies changes in rehabilitation status or transplant patient/graft survival data.	Networks have initiated numerous activities that support the overall care and participation of ESRD patients ranging from patient attitute surveys, informational materials, water treatment, emergency plans, organ procurement, staffing ratios and distribution of services. Frequently the need for developments in these areas evolves from or precedes more formal studies. Networks have responded to specific needs as they have arisen, such as management of complaints or placement of patients which may not be reflected in this summary.	Networks were not funded to initiate patient specific/ computerized data systems until January of 1981 when they assumed responsibility for MIS non-reimbursement forms. However, some established manual systems and others were able to draw on State Kidney Program registries. The status of networks in terms of data management, extent of data entry and size of the data base is included in this section. "Tracking" indicates access to patient specific data which is updated regularly and includes changes in facility, setting modality or patient status.
01 HONOLULU,HI HI,GU,AM.SAMOA,PACIFIC ISL. 08 0092 01 00363	Inclusion of patients in ESRD Programs (MCE)	Multidisciplinary Intervention (MCE) in process	Patient and family workshop "rap sessions"	Manual System 400+ current patients since 1978 Aggregate data on changes in status
02 SEATTLE,WA AK,ID,OR,MT,WA 24 0227 04 01282	Documentation of Long Term Program in Medical Records (MCE) Patients informed about and referred for transplant (MCE) -- criteria developed Social work assessment (MCE) -- criteria developed	Cadaveric transplant patient and graft survival at one year (MCE) -- life table display	Patient advisory committee Grievance procedures Patient education materials Patient satisfaction survey (special study) Network-wide emergency plan	Time sharing 1300 patients since 1980
03 SAN FRANCISCO,CA CA*,NV* 48 0554 03 02158	Indications for inclusions in ESRD Program (MCE) Creatinine levels of new ESRD patients (MCE) Standardized long term program form developed (monitoring)	CAPD Outcome (special study and monitoring) Hepatitis incidence and prevalence (monitoring) and referral (special study) Transplant patient and graft survival (MCE)	Patient Advisory committee Grievance procedures Management of complaints Patient/staff ratio (special study)	Time sharing 2,257 patients since 1981 Tracking of dialysis and transplant patients.

(CONTINUED)

NETWORK INFORMATION	APPROPRIATENESS OF CARE STUDIES	MORTALITY/MORBIDITY STUDIES	PATIENT/PROGRAM SUPPORT ACTIVITIES	DATA COLLECTION ACTIVITIES
	(continued) Referral for home training and transplantation (MCE) Workshop on long term program development	Emergency treatment for cardiac arrest (MCE) Interdialytic weight gain (Multidisciplinary MCE)		
04 LOS ANGELES,CA CA*,NV* 85 1074 11 03929	Characteristics of transplant candidates (profile analysis) Selection of patients for transplant (MCE) Selection and training of CAPD patients (MCE) and criteria development Required life plan form (monitored since 1978)	Hospitalization of post transplant patients (MCE) Hospitalization of ESRD patients (MCE) Hospitalization of peritoneal patients (special study) Hepatitis incidence and prevalence (MCE and monitoring)--surveillance guidelines Mortality by setting/modality and cause of death (profile analysis)	Role of social workers and dietitians in the care of ESRD patients (special study) -- standards set Home dialysis follow-up guidelines set Dialysis safety equipment (MCE) -- standards set Trends in incidence and prevalence by age, diagnosis, race, sex, and health planning area of residence (profile analysis)	Time sharing 7,000 patients since 1978 Tracking of dialysis and transplant patients
05 DENVER,CO CO,UT*,WY,NE* 27 0248 03 00842	Indication for inclusion in the ESRD Program (MCE) Appropriateness of selection for center dialysis, home training and living donor and cadaveric transplant (MCE)	Hospitalization of ESRD patients (MCE)	Patient Advisory Group Review of one facility in depth Staffing ratios Water quality standards Dialyzer reuse guideline	Time sharing Current 865 patients Tracking of dialysis and transplant patients
06 ALBUQUERQUE,NM AZ,NM,UT* 25 0231 05 00806	Selection for home dialysis (MCE) Selection for home dialysis and transplant (special study)--criteria	Transplant patient graft survival (profile analysis) Mortality by race and age (profile analysis) Post transplant rehabilitation status (MCE) Management of transplant patient for two months after discharge (in process)	Patient rights and responsibilities manual in English and Spanish Network plan	Radio shack since 1980 1,000 patients in data base
07 MINNEAPOLIS,MN MN,ND,SD,MI*,WI*, 26 0209 03 00721	Workshop on contraversies in self care and home dialysis Social work role in assessment and care planning (special study) guidelines set Admission to program and selection for home training and transplant (profile analysis and monitoring)	Bacteremia/infection (MCE) Mortality by cause of death, age, race, sex, primary diagnosis (profile analysis) Medical Review Board plan developed Dialysis and transplant and graft survival by same variables as mortality (life table analysis)	Incidence and prevalence by diabetic status, age, county of residence Organ procurement task force with patient involvement Grievance program in process Water testing quality/cost study	Time sharing Dialysis and transplant tracking since 1977 3,000 patients in data base

NETWORK INFORMATION	APPROPRIATENESS OF CARE STUDIES	MORTALITY/MORBIDITY STUDIES	PATIENT/PROGRAM SUPPORT ACTIVITIES	DATA COLLECTION ACTIVITIES
08 DES MOINES,IA IA,NE*,IL* 17 0167 02 00565	Initiatinn of patients on maintenance dialysis (MCE and monitoring) Frequency of dialysis (MCE and monitoring) Characteristics of dialysis population by age, race, sex and diagnosis (profile analysis) Referral of patients for home dialysis and transplantation (MCE and monitoring) Selection for CAPD (MCE)	Transplant patient and graft survival (profile anlaysis and monitoring) Rehabilitation status (special study) Osteodystrophy diagnosis and treatment (MCE) Transfusions in anemia treatment (MCE) Incidence and prevalence of hepatitis (monitoring)	Grievance committee Management of complaints Staffing patterns (special study) Organ recovery -- past, present, and projected (special study) Patient residence and distance travelled (special study and monitoring) Incidence and prevalence by setting, age, race, sex, primary diagnosis and patient HSA residence Cost study (special study)	Time sharing Dialysis and transplant tracking since 1977 Data base of 1,500 pts.
09 KANSAS CITY,MO KS,MO*,IL* 29 0336 08 01262	Team involvement in care of ESRD patients (MCE and monitoring) criteria Patients not selected for home dialysis and transplant (MCE) Characteristics of patients selected for home dialysis and transplant (profile analysis) Criteria for selection for home dialysis and referral for transplant	Utilization of certified ESRD hospitals for backup support (MCE) Utilization of non ESRD certified hospitals for backup (MCE) Transplant patient and graft survival (profile analysis) in process	Management of complaints Staff/patient relations (special study) standards set Organs procured and not used (special study) Prevalence by setting, by county of residence (profile analysis)	Manual system Tracking of dialysis and transplant patients 2,400 patients in data base
10 OKLAHOMA CITY,OK AR*,OK 31 0231 05 00730	Workshop on the development of the long term programs and patient care plans	Transplant patient and graft survival at one year (MCE) Frequency and duration of ESRD patient hospitalization (profile analysis) Infection incidence and treatment (MCE) and monitoring) Mortality by cause of death, sex, age, state of residence (profile analysis)	Grievance committee procedures developed Incidence by primary diagnosis, state of residence, age and sex (profile analysis) Prevalence by age, setting modality (profile analysis)	Manual system since 1978 1,200 patients in data base Aggregate data
11 RICHARDSON,TX TX 69 0948 07 03369	Psychosocial assessment (MCE) Nutritional assessment (MCE)	Pediatric and adolescent dialysis (MCE) Incidence and prevalence of hepatitis (MCE and monitoring) Transplant patient and graft survival (profile analysis) Hepatitis (profile analysis)	Patient advisory group Monthly prevalence and incidence (monitoring)	Manual management of aggregate data received through Texas State Kidney Program

NETWORK INFORMATION	APPROPRIATENESS OF CARE STUDIES	MORTALITY/MORBIDITY STUDIES	PATIENT/PROGRAM SUPPORT ACTIVITIES	DATA COLLECTION ACTIVITIES
12 BATON ROUGE,LA LA 26 0303 05 01032	Workshop on transplant potential, appropriateness review and feelings of patients on dialysis	Longevity of primary access for hemodialysis patients (MCE) Hepatitis profile analysis Hospitalization for three specific diagnoses (profile analysis) Mortality by age and diagnosis (profile analysis)	Patient responses to illness survey	Time sharing Data base of 1,100 patients since 1978
13 MILWAUKEE,WI WI* 21 0163 02 00646	Indications for inclusion of patients in the ESRD program (MCE) Selection and referral for transplant (MCE) -- form/plan developed Characteristics of new patients (profile analysis and monitoring)	Outcomes of patients in CAPD (MCE) Changes in occupational status after initiation of dialysis (special study) Incidence and prevalence of hepatitis and surveillance practices (special study and profile analysis) Mortality by race, sex, age and diabetic status (MCE) Hospitals backup utilization by diabetic status and discharge diagnosis (MCE)	Patient advisory group Patient attitude study - home dialysis and transplantation (special study) Effectiveness of nutritional intervention (MCE) in process	Time sharing Tracking of 700 dialysis patients since 1981
14 ANN ARBOR,MI MI* 33 0484 11 01737	Long term program development (MCE and monitering) Patient informed about home training and transplant (special study)	Life table analysis of hemodialysis patients Life table analysis of transplant patient and graft survival Vascular access survival for hemodialysis patients (MCE)	Patient/staff ratio (survey) Dialysis reuse (special study) Hours of operation (special study) Incidence and Prevalence by county of residence	Time sharing through Michigan state registry Data base since 1972 of 5,500 patients Tracking of dialysis and transplant patients
15 SPRINGFIELD,IL IL* 60 0754 07 02458	Patient entry into the ESRD program (MCE) Development of long term program and patient care plan forms Task force on home dialysis	Transplant patient and graft survival in process (MCE) Morbidity in dialysis patient by primary diagnosis (MCE and profile analysis) Adequacy of dialysis (MCE)	Grievance policies by MRB Patient education booklet Prevalence and incidence by HSA of residence, race, age and sex	Time sharing Tracking from data base of 2,642 patients since 1980
16 INDIANAPOLIS,IN IN 12 0208 03 00999	Initiation of dialysis (MCE) Characteristics of patient dialyzing at home or receiving a transplant (profile analysis)		Patient education materials on transplantation	Time sharing Tracking 2,000 patients since 1978

NETWORK INFORMATION	APPROPRIATENESS OF CARE STUDIES	MORTALITY/MORBIDITY STUDIES	PATIENT/PROGRAM SUPPORT ACTIVITIES	DATA COLLECTION ACTIVITIES
17 LEXINGTON,KY KY,OH* 22 0256 06 00956	Patient evaluation for treatment of ESRD (MCE) Development of long term program form (monitoring) Selection for home training or referral for transplant (MCE)-criteria Social work assessment (special study)	Transplant patient and graft survival at one year (profile analysis) Mortality of dialysis patients (profile analysis) Documentation of rehabilitation status (MCE)	Committee on Organ Procurement Patient/staff ratio recommendations Metabolic control (MCE)	Radio Shack Tracking of dialysis and transplant patients Data base of 2,400 patients since 1978
18 HENDERSONVILLE,TN AL*,MS,TN,AK*,GA*,MO*,VA* 58 0711 04 02437	Inclusion of patient in the ESRD Program (MCE) Characteristics of patient selected for home training or referred for transplantation (MCE) -- criteria development	Evaluation of factors affecting incidence of hepatitis (MCE) Mortality of dialysis patients in relation to number of treatments (MCE)	Management of complaints by MRB Water treatment procedures (MCE) Transportation resources and distances travelled (special study) Patient origin by county (profile analysis)	Time sharing 3,937 patients in data base since 1980 Tracking dialysis and transplant patients
19 TAMPA,FL FL 67 0885 04 02610	Appropriateness of initiation of dialysis (MCE) Documentation of long term programs and referral (monitoring) Referral patterns for transplants (MCE) Characteristics of patients selected for home training (profile analysis)	Mortality among dialysis patients (MCE) Utilization of hospital backup services (MCE) Development of hepatitis surveillance guidelines	Patient advisory committee Dialyzer reuse (special study) Patient satisfaction (special study) Emergency plan -- network-wide Organ Procurement - (special study) committee Transportation/distance travelled (special study) Patient origin (profile analysis) Promote brain death legislation	Time sharing Tracking 3,500 patients
20 ATLANTA,GA GA*,SC,AL* 47 0676 05 02123	Appropriateness of care (MCE) Characteristics of patients not selecting home training and transplantation and reason (special study/profile analysis)	Anemia management (MCE) Osteodystrophy diagnosis and treatment (MCE) ESRD patient hospital admission (profile analysis) Dialysis and transplant patient morbidity (profile analysis) Utilization of hospital backup services (profile analysis)	Patient advisory group Patient education manual Management of complaints Incidence and prevalence by county of residence (profile analysis)	Time sharing Data base of 3,150 since 1979 Tracking of dialysis and transplant patients

NETWORK INFORMATION	APPROPRIATENESS OF CARE STUDIES	MORTALITY/MORBIDITY STUDIES	PATIENT/PROGRAM SUPPORT ACTIVITIES	DATA COLLECTION ACTIVITIES
21 RALEIGH,NC NC 18 0316 05 01186	Documentation of patient informed and reasons for not selecting home training or transplant (MCE) Guidelines for long term program development Staff survey on documentation of long term program and patient care plans	Transplant patient and graft survival (profile analysis) since 1978 Diagnosis and treatment of osteodystrophy (MCE) criteria Incidence, prevalence and surveillance of hepatitis (special study and monitoring) Mortality by setting and modality (profile analysis and monitoring) Factors affecting recidivism among home patients (special study) Utilization of hospital and facility backup for home and center dialysis patients (profile analysis and monitoring)	Patient advisory committee Grievance procedure review -- guidelines Patient information manual in process Participation in Paid Aide Experiment Prevalence and incidence by county of residence (profile analysis and monitoring)	Apple II Manual tracking since 1978 of dialysis and transplant patients Data base of 2,300 patients All patients living with transplants as of 1/1/78
22 PITTSBURGH,PA OH*,PA* 43 0540 06 02038	Patient informed about home dialysis and transplant (MCE) Patients placed on cadaveric waiting list (monitoring) Psychosocial assessment (MCE)	Adequacy of dialysis (MCE) Blood access survival (MCE) Rehabilitation status of transplant patients (MCE) Hepatitis incidence (profile analysis) Quality of pediatric dialysis program (MCE) Surgical complication of transplant patients (MCE) Mortality by age, race, sex for dialysis and transplant patients (profile analysis)	Patient advisory group Patient satisfaction survey Grievance procedures Network-wide emergency plan Organ procurement committee	Manual system since 1978 Data base of 2,302 patients
23 CHEVY CHASE, MD DC,VA*,MD* 22 0288 05 00988	Admission to the ESRD program (MCE) Referral for home training and transplant (MCE) - criteria Patients referred to home training or transplant (profile analysis) Informed consent (MCE) Long term program (monitoring/site visit) - documentation criteria Workshops on long term program and patient care planning CAPD selection and training (special study) criteria	Mortality for each facility by modality, age, cause of death (profile analysis) Characteristics of home patients (special study)	Patient advisory council Patient and family attitude survey Patient information booklet Patient telephone line Grievance procedures Rehabilitation resource survey Staffing ratios for physicians, nurses and technicians - criteria Medical equipment and supplies - criteria Transplantation cost (special study) Incidence and Prevalence (profile analysis)	Time sharing Tracking 1,500 dialysis patients since 1980

NETWORK INFORMATION	APPROPRIATENESS OF CARE STUDIES	MORTALITY/MORBIDITY STUDIES	PATIENT/PROGRAM SUPPORT ACTIVITIES	DATA COLLECTION ACTIVITIES
24 KING OF PRUSSIA, PA DE,PA* 52 0647 07 02322	Patients informed about home dialysis and transplant (MCE) Documentation of long term program and patient care plan (MCE) form developed (monitoring)	Rehabilitation survey by social workers (special study) Transplant patient and graft survival for one year (profile analysis) Incidence and prevalence of hepatitis (special study) Five year review of mortality of facility dialysis patients (profile analysis) Incidence of diabetic neuropathy (MCE)	Patient education materials Education needs for nurses and technicians (survey) Staff shortages (survey) Transportation--distance travelled survey	Manual system Tracking of transplant patients
25 NEW YORK, NY NY* 58 0713 06 03756	Selection for home training and referral for transplant (MCE) Characteristics of new ESRD patients (profile analysis) criteria	Transplant patient and graft survival at one year (profile analysis and monitoring) Mortality of dialysis patients (profile analysis/special study) in process Hospitalization of dialysis patients (profile analysis) in process Longitudinal study of blood pressure control in hemodialysis patients (special study)	Grievance committee--required policies Network nursing, social work and nutritional advisory committees Network-wide emergency plan Prevalence by zip of residence and referral patterns (profile analysis)	DEC Micro Processor Data base of 3,000 patients since 1978
26 LIVERPOOL, NY NY*,PA* 23 0169 06 00990	Inclusion of patients in ESRD program (MCE) Selection for home training or referral for transplant (MCE) Committee on home training Workshop on home training	Infection control (MCE) Predialysis status of ESRD patients (profile analysis) Incidence and prevalence of hepatitis patients (profile analysis) in process Transplant patient and graft survival (profile analysis) in process Rehabilitation status (special study)	Organ procurement committee Water testing procedures (MCE) guidelines	DEC Micro Processor shared with Network 25 and New York Kidney Institute Tracking manually 1,100 patients since 1978
27 NEW HAVEN, CT CT 14 0162 02 00699	Long term program (monitoring through site visits) Transplantation and home dialysis as treatment options (MCE) Model form for long term program Psychosocial and nutritional assessment (MCE) criteria set	CAPD outcomes and infection control (MCE) Protocols for hepatitis management, prevention and surveillance (monitoring) Mortality of dialysis and transplant patients via life table analysis Osteodystrophy diagnosis and treatment (MCE) Infection control (MCE)	Patient information manual Standards for training nurses and technicians On call nursing schedules (special study) Administrative role of nurses (special study) Role of infectious disease control (special study) Nutritional status (MCE) Incidence and prevalence by county of residence, age, race and sex (profile analysis)	Time sharing Tracking of dialysis and transplant patients since 1977

NETWORK INFORMATION	APPROPRIATENESS OF CARE STUDIES	MORTALITY/MORBIDITY STUDIES	PATIENT/PROGRAM SUPPORT ACTIVITIES	DATA COLLECTION ACTIVITIES
28 BOSTON, MA ME,MA,NH,RI,VT 33 0377 09 01900	Survey of treatment regimen for patients with chronic renal failure	Duration and frequency of dialysis (profile analysis) Rehabilitation status pre and post (special study)	Patient dietary handbook Renal dietitians handbook Demographic and travel distance (special study)	Manual
29 RIO PIEDRUS,PR PR,VI 14 0137 01 00675	REPORT NOT RECEIVED AT TIME OF THIS REPORT		Quality of dialysis fluids (MCE)	
30 RICHMOND, VA VA-WV 40 044 04 01520	Referral for transplantation and selection for home training (MCE) Site visit and record review of facilities planning to expand (monitoring) Workshop on selection, training and follow-up of home patients Workshop on referral and outcomes of transplantation	Transplant patient and graft survival (profile analysis) Anemia management (MCE) Osteodystrophy diagnosis and treatment (MCE) Volume control with dialysis (MCE) Vascular access procedures (MCE) Hepatitis control (MCE) Outpatient dialysis outcome (profile analysis) Metabolic control of ESRD patients (MCE)	Patient advisory committee Medication procedure Organ procurement committee Patient satisfaction survey	Manual system Aggregate data on 1,700 patients since 1980
31 BALTIMORE,MD MD* 15 0158 03 00565	Admission to ESRD program (MCE) Selection for home training and referral for transplant (MCE) Network screening forms to monitor selection for home training and transplantation (monitoring)	Non-diabetic, cadaveric transplant patient and graft survival at one year (MCE)	Grievance procedures Water quality testing criteria Established Network-wide organ procurement agency	Manual Data base of 850 patients since 1980 Tracking of dialysis patients
32 EAST BRUNSWICK, NJ NJ 26 0361 03 01959	Referral for transplantation (MCE) Patient access to home training (MCE) Team participation in selection of treatment modality (MCE) Review deficiency reports for ESRD facility surveys (monitoring of long term programs) Nutritional assessment (MCE)	Review of diagnostic laboratory studies (profile analysis) CAPD morbidity (profile analysis) Transplant patient and graft survival (profile analysis) Hospitalization for vascular access revisions (MCE)	Patient advisory group Patient rights and responsibilities Grievance procedures Model agreements and arrangements for hepatitis referral and CAPD training Patient/staff ratios Vocational rehabilitation needs assessment (monitoring utilization of vocational rehabilitation)	DEC Micro processor Tracking of 2,000 patients since 1978

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Senator DURENBERGER. Dr. Lyons, you will be next.

STATEMENT OF PATRICIA J. LYONS, M.D., CHAIRPERSON, AND RONALD WRONA, PH. D., EXECUTIVE DIRECTOR, NETWORK NUMBER 24, KING OF PRUSSIA, PA.

Dr. LYONS. Thank you.

Networks were created to provide a mechanism by which the providers in the private sector and the Federal Government could cooperate to provide maximum quality of care to the end stage renal disease patients at a reasonable cost.

The unique structure of the networks insures high quality expertise at a local level in the various disciplines involved in end stage renal disease care. The activities of the individual networks have provided quality assurance, assured appropriate utilization and distribution of resources, encouraged home dialysis, transplantation, and rehabilitation of patients, and provided a mechanism by which patients may participate in the ESRD decisions.

The networks have the potential for testing new approaches to policies relative to delivery of care and reimbursement.

It has been the experience of our network that an educational consensus-building approach to the providers and to the patients leads to significant local improvements in the medical care system. For example, 25 percent of all new end stage renal disease patients in our network now complete a self-dialysis training program as opposed to approximately 10 percent in 1978.

Public Law 92-603 established the ESRD program with a mixed pattern of subsidy for care and regulation to insure accessibility and quality. There were problems from the outset in embedding the ESRD program into the medicare reimbursement principles and procedures.

Dialysis became defined as an ancillary service. Dialysis machines and transplanted organs are classified by medicare with items such as limb prostheses and tissue banks. Some of the disincentives for home dialysis and transplantation are simply byproducts of this classification. Many problems in rate setting also derive from these definitions.

The concept behind the reimbursement principles and the procedures portrays the chronic renal disease beneficiary as an individual who is basically healthy but who needs periodic dialysis or a kidney transplant to stay alive. But end-stage renal disease patients are chronically ill.

Renal failure itself adversely affects all of the body systems. The recent increase in patients entering the program with other serious underlying diseases, such as diabetes mellitus, further complicates the problem.

The disparity between the "healthy" definition in the medicare structure and the reality of chronic illness has created difficulty in establishing equitable reimbursement schedules for the various types of ESRD treatment, such as hospital-based versus facility-based hemodialysis, intermittent peritoneal dialysis, and CAPD.

Public Law 95-292 recognized some of these shortcomings and attempted to rectify them. In particular, it created network organizations for the purpose of assuring effective and efficient administration of the benefits.

Network number 24 sees the law as giving local organizations a share in the administration of the ESRD program and, in particular, in selecting the most appropriate local means for achieving the intent of Congress "that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantations should be so treated."

Despite considerable opposition from the bureauracy, Network 24 has continued to use an educational rather than a regulatory approach to effect changes in the use of home dialysis or transplantation. Our success can be attributed, in part, to the physician experience in rationing care which antedates medicare reimbursement. Our success in this endeavor has been gratifying.

The number of patients receiving care at home has increased 71 percent since 1978, and the number of transplant operations has increased 18 percent between 1978 and 1980.

The interaction between the networks and the Federal Government is critical to fulfilling the intent of Public Law 95-292. The interface between the networks and HCFA is far from ideal.

The responsibility and relative authority of HCFA and the networks needs clarification. There is a tendency for HCFA to use the network budgetary process to insure compliance with highly structured, centrally conceived, required activities. This sometimes interferes with local preferences for achieving the mutual goals.

At present, there is no appeals process to deal with disputes between the individual networks and HCFA.

In summary, our experience with the network system has been gratifying. We have attempted to identify some problem areas and bring them to the attention of the Federal Government.

Networks need more latitude for local decisionmaking in pursuing program goals of improved quality of care and cost containment. This should include the establishment of an appeals process.

Thank you.

Senator DURENBERGER. Thank you, Dr. Lyons.

[The prepared statement of Patricia J. Lyons, M.D., follows:]

TESTIMONY TO: FINANCE COMMITTEE HEARING
PRESENTED BY: PATRICIA J. LYONS, M.D., CHAIRPERSON NETWORK NO. 24
HEARINGS ON: END-STAGE RENAL DISEASE COUNCILS (NETWORKS)
DATE: SEPTEMBER 28, 1981

NETWORKS WERE CREATED TO PROVIDE A MECHANISM BY WHICH THE PROVIDERS IN THE PRIVATE SECTOR AND THE FEDERAL GOVERNMENT COULD COOPERATE TO PROVIDE MAXIMUM QUALITY CARE TO THE END-STAGE RENAL DISEASE PATIENTS AT REASONABLE COST.

THE UNIQUE STRUCTURE OF NETWORKS ENSURES HIGH QUALITY EXPERTISE AT A LOCAL LEVEL IN THE VARIOUS DISCIPLINES INVOLVED IN ESRD CARE. THE ACTIVITIES OF THE INDIVIDUAL NETWORKS HAVE PROVIDED QUALITY ASSURANCE, ASSURED APPROPRIATE UTILIZATION AND DISTRIBUTION OF RESOURCES, ENCOURAGED HOME DIALYSIS, TRANSPLANTATION AND REHABILITATION OF PATIENTS AND PROVIDED A MECHANISM BY WHICH PATIENTS MAY PARTICIPATE IN ESRD PROGRAM DECISIONS. NETWORKS HAVE THE POTENTIAL FOR TESTING NEW APPROACHES TO POLICIES RELATIVE TO DELIVERY OF CARE AND REIMBURSEMENT. IT HAS BEEN THE EXPERIENCE OF OUR NETWORK THAT AN EDUCATIONAL CONSENSUS-BUILDING APPROACH TO THE PROVIDERS AND PATIENTS LEADS TO SIGNIFICANT LOCAL IMPROVEMENTS IN THE MEDICAL CARE SYSTEM. FOR EXAMPLE, 25% OF ALL NEW ESRD PATIENTS NOW COMPLETE A SELF-DIALYSIS TRAINING PROGRAM AS OPPOSED TO APPROXIMATELY 10% IN 1978.

P.L. 92-603 ESTABLISHED THE ESRD PROGRAM WITH A MIXED PATTERN OF SUBSIDY FOR CARE AND REGULATION TO ENSURE ACCESSIBILITY AND QUALITY. THERE WERE PROBLEMS FROM THE OUTSET IN EMBEDDING THE ESRD PROGRAM INTO THE MEDICARE REIMBURSEMENT PRINCIPLES AND PROCEDURES. DIALYSIS BECAME DEFINED AS AN ANCILLARY SERVICE. DIALYSIS MACHINES AND TRANSPLANTED ORGANS ARE CLASSED, BY MEDICARE, WITH ITEMS SUCH AS LIMB PROSTHESES AND TISSUE BANKS. SOME OF THE DISINCENTIVES FOR HOME DIALYSIS AND TRANSPLANTATION ARE SIMPLE BY-PRODUCTS OF THIS CLASSIFICATION. MANY PROBLEMS IN RATE-SETTING DERIVE FROM THESE DEFINITIONS.

THE CONCEPT BEHIND THE REIMBURSEMENT PRINCIPLES AND PROCEDURES PORTRAYS THE CHRONIC RENAL DISEASE BENEFICIARY AS AN INDIVIDUAL WHO IS BASICALLY HEALTHY BUT NEEDS PERIODIC DIALYSIS OR A KIDNEY TRANSPLANT TO STAY ALIVE. END-STAGE RENAL DISEASE PATIENTS ARE CHRONICALLY ILL. RENAL FAILURE ITSELF ADVERSELY AFFECTS ALL OF THE BODY SYSTEMS. THE RECENT INCREASE IN PATIENTS ENTERING THE PROGRAM WITH OTHER SERIOUS UNDERLYING DISEASES, SUCH AS DIABETES MELLITUS, FURTHER COMPLICATES THE PROBLEM. THE DISPARITY BETWEEN THE "HEALTHY" DEFINITION IN THE MEDICARE STRUCTURE AND THE REALITY OF CHRONIC ILLNESS HAS CREATED DIFFICULTY IN ESTABLISHING EQUITABLE REIMBURSEMENT SCHEDULES FOR THE VARIOUS TYPES OF ESRD TREATMENT, SUCH AS HOSPITAL BASED VS. FACILITY BASED HEMODIALYSIS, INTERMITTENT

PERITONEAL DIALYSIS AND CAPD.

P.L. 95-292 RECOGNIZED SOME OF THESE SHORTCOMINGS AND ATTEMPTED TO RECTIFY THEM. IN PARTICULAR, IT CREATED NETWORK ORGANIZATIONS "FOR THE PURPOSE OF ASSURING EFFECTIVE AND EFFICIENT ADMINISTRATION OF THE BENEFITS." NETWORK NO. 24 SEES THE LAW AS GIVING LOCAL ORGANIZATIONS A SHARE IN THE ADMINISTRATION OF THE ESRD PROGRAM AND IN PARTICULAR IN SELECTING THE MOST APPROPRIATE LOCAL MEANS FOR ACHIEVING THE INTENT OF CONGRESS "THAT THE MAXIMUM PRACTICAL NUMBER OF PATIENTS WHO ARE MEDICALLY, SOCIALLY AND PSYCHOLOGICALLY SUITABLE CANDIDATES FOR HOME DIALYSIS OR TRANPLANTATIONS SHOULD BE SO TREATED." DESPITE CONSIDERABLE OPPOSITION FROM THE BUREAUCRACY, NETWORK 24 HAS CONTINUED TO USE AN EDUCATIONAL RATHER THAN A REGULATORY APPROACH TO EFFECT CHANGES IN THE USE OF HOME DIALYSIS AND TRANSPLANTATION. OUR SUCCESS CAN BE ATTRIBUTED, IN PART, TO THE PHYSICIAN EXPERIENCE IN RATIONING CARE WHICH ANTEDATES MEDICARE REIMBURSEMENT. OUR SUCCESS IN THIS ENDEAVOR HAS BEEN GRATIFYING. THE NUMBER OF PATIENTS RECEIVING CARE AT HOME HAS INCREASED 71% SINCE 1978. THE NUMBER OF TRANSPLANT OPERATIONS IN NETWORK 24 INCREASED 18% BETWEEN 1978 AND 1980.

THE INTERACTION BETWEEN THE NETWORKS AND THE FEDERAL GOVERNMENT IS CRITICAL TO FULFILLING THE INTENT OF P.L. 95-292. THE INTERFACE BETWEEN THE NETWORKS AND THE HEALTH CARE FINANCING

ADMINISTRATION IS FAR FROM IDEAL.

THE RESPONSIBILITY AND RELATIVE AUTHORITY OF HCFA AND NETWORKS NEEDS CLARIFICATION. THERE IS A TENDENCY FOR HCFA TO USE THE NETWORK BUDGETARY PROCESS TO ENSURE COMPLIANCE WITH HIGHLY STRUCTURED, CENTRALLY CONCEIVED REQUIRED ACTIVITIES. THIS SOMETIMES INTERFERES WITH LOCAL PREFERENCES FOR ACHIEVING THE MUTUAL GOALS. AT PRESENT THERE IS NO APPEALS PROCESS TO DEAL WITH DISPUTES BETWEEN INDIVIDUAL NETWORKS AND HCFA.

IN SUMMARY, OUR EXPERINECE WITH THE NETWORK SYSTEM HAS BEEN GRATIFYING. WE HAVE ATTEMPTED TO IDENTIFY SOME PROBLEM AREAS AND BRING THEM TO THE ATTENTION OF THE FEDERAL GOVERNMENT.

NETWORKS NEED MORE LATITUDE FOR LOCAL DECISION MAKING IN PURSUING PROGRAM GOALS OF IMPROVED QUALITY OF CARE AND COST-CONTAINMENT. THIS SHOULD INCLUDE THE ESTABLISHMENT OF AN APPEALS PROCESS.

THANK YOU.

Senator DURENBERGER. Dr. Pfaff?

STATEMENT OF WILLIAM PFAFF, M.D., CHAIRMAN OF THE MEDICAL REVIEW BOARD OF THE FLORIDA ESRD NETWORK, DIRECTOR OF THE TRANSPLANTATION PROGRAM, SHANDS TEACHING HOSPITAL, GAINESVILLE, FLA.

Dr. PFAFF. I am going to depart from a previously prepared summary and really try to bring the focus, perhaps reiterating some of the things that have already been said, perhaps with a different view.

Much of what I am going to talk about is based on the end-stage renal disease network in Florida, Network 19. First, it is a little peculiar for a surgeon to be talking about a bunch of nephrologists, but that is really what most networks are made up from.

I also want to answer your question. You said, why do you need all this data? Are you a bunch of data freaks or just what? Well, in effect, we need it to make decisions. These are two changing technologies, dialysis and transplantation. There have been remarkable changes in recent years. There is a remarkable change this year.

We don't know yet about CAPD. We don't know how safe it is. We need to keep judging that over and over. We need to tell our fellows about it when those changes occur.

We prepared a number of studies. When we started doing studies in our network, we were lousy at it. We did a terrible job. And we found out that most of our charts were no good. We learned to rechart. We learned to develop better medical records. From that, we started asking serious questions: Why are people transplanted and why aren't they? We found that really as much as a third of our population, which skews a little bit toward the elderly, are potentially transplant candidates. We were only transplanting, and even now, a little less than 10 percent. Why was that? We found in most of it that the patients were concerned about mortality rates.

Well, we had already started studying mortality rate after transplantation. In your appendix of the written testimony there is a comparison of dialysis and transplantation addressing risk factors: diabetes, age. There are many others that aren't included in the tables, in the limited number of tables that we have given to you. It does address all of those for dialysis.

We are going to send you more about transplantation. Dr. Davis said that they have been unable to provide us via the medical information system this kind of information. We have wanted it since 1974 when the NIH Registry was closed down with a promise that we were going to have an effective mechanism. We have not had an effective mechanism over all those years. We need it to make decisions.

Senator **Durenberger**. Is this the feedback that Dr. Gutman referred to earlier?

Dr. **Pfaff**. I think so, yes. You will hear that from every nephrologist and every transplant surgeon in the country, "Where is our data?"

There has been discussion about responsibility of the networks, how did that evolve. Well, there are some regulations that were originally described. But actually the principle goes beyond those regulations. It is something that all has perhaps been stirred by different administrations in recent years.

Can local individuals take responsibility for local problems? We said yes. We said we are pros; we know what we are doing. We had to learn a little bit about regulations and reimbursement and intermediaries. We didn't know what any of those words meant. We know them now.

We have learned how to do studies accurately and well. We even know what medical care evaluation studies are, peer review, quality care. We used to say taking good care of patients and we have all these code words for it now.

I would like to address cost for one second. I work for the network for lunch and gas. That is my return. I spend a fair amount of time at it because I am interested in it.

While I am an educator, all of us are. Are these experiments? Every management of every patient is an experiment. And if we don't learn from it, if we don't modify our actions from the care of every patient, we are not going to learn, we are going to remain stupid. We prefer not to remain stupid.

I would echo Dr. Sadler's comments, we don't work for money. Well, we like to be comfortable. We are comfortable. And being a little bit more comfortable is not that important to most of us.

To put all of that together—there are 20 other things I would like to comment about, about some of the things I have heard today—I would say that we can perform quality of care in networks. We have altered behavior. We have changed the organization of individual programs. Our quality of care is dependent on good data. We have not been able to get good data from Washington or Baltimore. We can get good data from Tampa, Fla., where our network is headquartered.

We can be liaisons with the patient. We do that now. We have a patient advisory committee. We have an officer, the vice chairman of the organization, who is a patient. We hear from them and we need to. They tell us where to go, usually in a good direction.

Thank you.

Senator DURENBERGER. Thank you very much.

[The prepared statement of William Pfaff, M.D., follows:]

TESTIMONY BY WILLIAM PFAFF, M.D. CONCERNING ACCOMPLISHMENTS OF END-STAGE RENAL DISEASE NETWORKS

Mr. Chairman and members of the committee, I am William Pfaff, M.D. of Gainesville, Florida. I am a professor of surgery at the University of Florida and Director of the Kidney Transplantation Program. I serve as Chairman of the Medical Review Board of the Florida End Stage Renal Disease Network and also head its Transplantation and Organ Procurement Task Force.

I would like to address, in some detail, two of the areas that you have selected for discussion today: (1) the current status and potential future role of the ESRD Networks, and (2) the need for medical and scientific data for clinical and programmatic uses.

NETWORK MISSION

End Stage Renal Disease (ESRD) Networks, mandated by Section 1881 of the Social Security Act, have, I believe, fully demonstrated their value in efficiently and effectively bringing about improvements in the operation of the nationwide ESRD program. An examination of Networks' accomplishments during the relatively short period of their existence gives support to this statement.

The Network concept as we in the Florida ESRD Community envision it, is based on the premise that ESRD professionals, given the opportunity, have the ability and interest to respond effectively to the special needs and problems of individuals with irreversible kidney failure.

The Network may be described as a self-regulating structure wherein patients, physicians, nurses, dietitians, social workers and administrators can come together to solve problems that cannot be resolved by an individual practitioner, facility or patient acting alone. It is also an important force for interfacing with government in implementing needed changes including the moderating of costs in the delivery of ESRD care in the United States.

In reviewing for you the past performance and achievements of the ESRD Networks, I am forced to rely on my own personal experience. There is little question that it took considerable effort to meld the many diverse elements of the Florida ESRD program into a functioning and effective organization. Most of us ESRD professionals participated in professional societies or medical associations that had sharply drawn objectives. Now, in our capacity with the Florida ESRD Network, we have had to (1) quickly learn about government rules and regulations; (2) how to establish an effective peer review mechanism to address the always thorny issue of assessing the quality of care provided by our colleagues; (3) develop new ways to disseminate information and educate members of the ESRD community concerning the latest technology and scientific innovations and (4) establish new avenues of communication with patients to resolve patient grievances. I submit that we have learned to perform these tasks well and are doing them on a fairly minimal investment. Without regard to the order of importance, I would like to comment on the various functions of the Networks.

INTERFACE WITH GOVERNMENT

Most Florida dialysis facilities and transplantation programs are generally small units encompassing one or two physicians and a limited number of supporting health professionals. In many communities, only one ESRD facility exists. The many sets of rules and regulations that are proposed and issued by the governmental bodies and fiscal intermediaries are confusing to many of us. In this connection, our Network has performed an important function in clarifying these issuances at the local level. Similarly, it has also served as a "voice" to government and the intermediaries by communicating the attitudes and reactions of the , ESRD professionals concerning these proposals.

QUALITY ASSURANCE

Within our Network, as well as in other Networks, ESRD providers have developed self-regulating criteria, standards and guidelines so as to monitor ESRD patient care, which, in turn, has helped to ensure the delivery of a high level of quality care. Such guidelines and performance review mechanisms are essential if the Networks are to exercise a leadership role in ensuring effective delivery systems of quality care for ESRD patients.

In Florida, efforts in the area of quality assurance have been greatly facilitated by the application of the Medical Review Board (MRB) mechanism. The MRB has played a key role in carrying out self-regulation that is an essential principle of the Network concept. Through such self-regulatory activities as medical care evaluation studies and profile analyses, our MRB has achieved a high level of success in ensuring the delivery of quality care to Florida ESRD patients. In the brief existence of Network Nineteen, we have discovered physicians, nurses and other members of the ESRD team of professionals are more responsive to suggestions and recommendations from their peers, rather than an expert from afar, including those from governmental agencies. Through such voluntary efforts by providers, the need for external regulatory controls may be lessened.

As we matured as a Network organization, we initiated the obligatory medical care evalution studies (MCE). Our first efforts were disastrous, for we found that record keeping in Florida ESRD faciities was insufficient to answer many of the critical questions. We learned that one of our first tasks would be to upgrade the quality of medical records. To this end the MRB developed a model set of medical records which were forwarded to each dialysis unit in the Network for adoption. Since this early effort, data collected from Florida ESRD facilities are found to be significantly more reliable and valid. Consequently, the quality of our medical care evaluations has been greatly improved.

Our next major effort was somewhat more complex. Prior to the creation of the Network, Florida ranked low among the 32 Networks with regard to the number of transplants performed. We were determined to reverse this trend. To do so, we concluded that critical baseline data was needed in order for physicians to make sound judgements as to the suitability of patients for transplantation and to assist Network facilities in the establishment of goal statements for improvement. In so doing, we established a registry of every patient on dialysis and those patients transplanted within the state. We soon learned that many patients were not being referred for transplantation because of the uncertainties regarding the procedure. Both patients and physicans were concerned regarding the relative risk of transplantation versus dialysis and what factors influenced that risk. A study to address this issue has been completed by our MRB and the data is included as an Appendix. Briefly, all Florida patients who were on dialysis at the initiation of the study were tracked for 12 months after being identified as to age, sex, race, mode of dialysis, location of facility, presence or absence of diabetes, cause of renal failure, and duration on dialysis. Patients transplanted during the same period have been used for comparison, addressing two major risk factors: age and diabetes. Our conclusions were that for a normal risk individual, mortality following transplantation was not higher than that of dialysis. This information is being made available to all ESRD facilities and their staff to ensure that objective information concerning transplantation and dialysis including risks and benefits will be appropriately conveyed to ESRD patients. As a direct result of these efforts, Florida's transplantation level had increased 25 percent in 1980 over the 1977 level.

The establishment of criteria and standards for home dialysis and the monitoring of progress toward target goals has had similar positive results. For example, there has been a 120 percent increase in the level of patients trained for home dialysis over the period 1978 to 1980. Data results are contained in the Network Nineteen 1980 Annual Report attached as an Appendix.

DATA FOR CLINICAL AND PROGRAMMATIC ACTIVITIES

Essential to the management of a program as complex as that of the Florida End Stage Renal Disease Program is the availability of accurate, timely, and appropriate data. The collection and analysis of data provides an essential guide to medical decisionmakers regarding treatment options and also offers management a vital tool in promoting and monitoring lower cost but of equal quality, treatment modalities.

The universal request of virtually all Florida Network facilities and their staff was for information regarding current, comparative patient outcomes so assound data base.

Since the Office of Special Programs assigned broad data responsibilities over to the Florida ESRD Networks and the funds to operate its own Network-wide MIS, the quality of data has improved. One indication of the success of this change is the 100 percent compliance achieved in 1980 and 1981 facility survey reporting.

In each of the studies that we have completed in Network Nineteen, we have found that there were rarely willful shortcomings among the facilities and ESRD practitioners. We did find a need for education on occasion, of both patients and facility staffs. Through a process of correction through education, we have witnessed positive changes in medical practices. Further, with an appreciation of the relative risks of mortality and morbidity of dialysis and transplantation, there has been a heightened referral for transplantation of suitable patients. By the same token, the transplant programs have recognized the limits of organ grafting with the tools now available to us and the relative stability of risk in the dialysis population.

PATIENT PARTICIPATION

We are constantly influenced by feedback from ESRD patients. In our Network, a Patient Advisory Committee has been established and has influenced a number of Network studies and special initiatives. At the recommendation of the Patient Advisory Committee, the MRB has initiated a study on dialyzer reuse. One of the products to be developed from this study is the refinement of existing Network guidelines governing the reuse of dialyzers and the establishment of new quantative standards for sterilization techniques and procedures.

The patient committee is currently participating in an advisory role to the MRB in a study on ESRD patient rehabilitation. The objectives of the investigation are to identify and eliminate existing barriers as well as promote the development of incentives for increased successful patient rehabilitation.

Network Nineteen also involves patients in the management process and provides an opportunity for their voices to be heard through the membership of the Network Coordinating Council and Executive Committee. In our Network, patients have become Council officers and thus have a prominent share in Network decisionmaking. The Vice-Chairman of Network Nineteen is a successful transplant patient.

Finally, patients need an appeal mechanism when a dispute arises with their physician or facility. The Network staff and members of the MRB and Patient Advisory Committee have repeatedly been able to resolve problems and disputes with suprisingly little rancor or resentment. Peer pressure by the Network is found to be effective in guaranteeing access to care and assuring that the patient is provided for in an appropriate manner and at a convenient site.

COST EFFECTIVENESS OF NETWORKS

Money budgeted for Network activity (4.5 million dollars) is a ridiculously small fraction of the 1.2 billion dollars anticipated for governmental costs of ESRD patients in the forthcoming year. In the main, I think this money for the Networks has been a remarkable investment as the Networks have, among many other accomplishments, secured millions of dollars of volunteer service by physicians, nurses, social workers and other ESRD professionals who have served without compensation on the Coordinating Councils, Executive Committees, Task Forces and special projects. The government has obtained expertise at a Network level for often no more than a free lunch, or at the most, travel costs. The framework of the Network's administrative staff has been the glue to organize and prepare for these important activities. The product, in my judgment, has been a superb bargain.

All of the components that I have listed are necessary for the rational conduct of the ESRD program. There has to be some provision for continuing these activities if we are going to do a good job of taking care of patients with renal failure, and if we are going to return these patients to a useful life. If we do not maintain some kind of structural framework, such as the Networks, I am sure we will continue to make slow progress, scratching for information and help in an individual fashion. I think we can do it faster and better with the Network organization. The Networks in my personal experience, have worked well, have been accorded a favorable reception by the professional community and by the patients and are remarkably cost effective.

Senator DURENBERGER. Mr. Bochnek?

STATEMENT OF HOWARD BOCHNEK, EXECUTIVE DIRECTOR, ESRD NETWORK NO. 25, INC., NEW YORK, N.Y.

Mr. BOCHNEK. Thank you, Mr. Chairman.

My written testimony addresses several issues. I will confine my remarks at this time to just the subject of networks.

Networks essentially are a resource of people out in the community. Networks represent the people at the grassroots level who receive medical care for end-stage renal disease and the providers who provide that care to the patients.

What we need in this program is less central control, less central regulation, less Government, and less involvement from the Department of Health and Human Services.

The appropriate role for the Department is the making of financial decisions and entitlement decisions: how much money we have to spend on end-stage renal disease, how that money should be spent, who should be entitled, and who those providers should be.

The role of Government really can go very little beyond that. The appropriate role of the network, that is the providers of care and the patients, is to report back to the Government to tell you what is happening with the money; to tell you what is happening with the program; and to tell you what is happening, most importantly, with the survival of the patients.

Networks have been a stepchild both to the Department of Health, Education, and Welfare and the Department of Health and Human Services. As I stated in my written testimony, we have been shuttled back and forth under four Presidents, under six different administrators, and several Secretaries. We have been bounced around a bit like a rubber ball with nobody willing to take responsibility, to look at this program, or to look at what networks have done.

Networks have suffered greatly from being criticized for what we supposedly have not done, while at the same time we have been prohibited from engaging in most of those activities.

Dr. Rettig has constantly criticized networks for not participating in direct facility hands on review. When our network tried to do that in 1978, we were informed by the then Director of the Office of Network Administration "you send a doctor into a facility and we will have them call the police and throw you out."

It has only been within the past 18 months that the Office of End Stage Renal Disease Services has worked cooperatively with networks in an attempt to straighten out the problems that we have had in the system. Despite the lack of central focus and direction that networks have had in the past several years, we have made significant contributions to the program. We have had an enormous impact on this program. Unfortunately, nobody in the Health Care Financing Administration reads the reports that are sent in by the networks.

We, meaning the networks, will be submitting, to be entered into the written record, a summary of what networks have done, what networks have accomplished.

[See attachments to testimony of Robert Gutman, M.D.]

Mr. **Bochnek**. If you wish to see the background material from which that was gathered; those are the network annual reports which have been submitted to HCFA for the past 4 years, which no one has read. The earlier testimony from the administration today testifies to that fact.

My written testimony, as you see, is very critical of Dr. Carolyne Davis. I was delighted to hear one of her statements today, which in and of itself might be the best reason for continuing networks.

Dr. Davis said that things have turned around in the area of data gathering and the gathering of information for the end stage renal disease program. There is a new system which they have instituted in the past year that now for the first time is gathering information. For the first time providers are submitting that information. For the first time facility surveys are being completed and the data is being validated.

Well, I applaud Dr. Davis for noting those changes in the system. What she did not answer in response to your question; is that the mechanism has been to turn over the responsibility to networks at the beginning of this past year.

HCFA has no data. I will qualify that by saying no validated and accurate data on this program, other than the data that end-stage renal disease networks have validated and have provided to the administration. As I said, we will be providing a summary of the other accomplishments of networks, and we will be happy to provide you with the hundred pounds or so of other material if the committee desires to conduct an independant review.

Thank you very much, Mr. Chairman.

Senator **Durenberger**. Thank you very much.

[The prepared statement of Howard J. Bochnek follows:]

TESTIMONY OF HOWARD J. BOCHNEK

THE END STAGE RENAL DISEASE PROGRAM HAS BEEN UNDER THE SUCCESSIVE ADMINISTRATIVE SUPERVISION OF THREE BUREAUS AND OFFICES AND HAS HAD NO FEWER THAN FOUR PROGRAM DIRECTORS AND DIRECTORS OF NETWORK ADMINISTRATION. THE OFFICE OF SPECIAL PROGRAMS, ALONE HAS HAD THREE DIRECTORS SINCE THE OFFICE WAS CREATED TWO YEARS AGO. IT HAS ONLY BEEN SINCE THE END OF 1979 THAT THE PROGRAM HAS BEEN ADMINISTERED BY A TEAM THAT HAS BEEN SUPPORTIVE OF THE NETWORK CONCEPT.

HCFA ADMINISTRATOR, DR. CAROLYN DAVIS IS CURRENTLY PROCEEDING WITH A REALIGNMENT OF HCFA, ADDING ANOTHER LEVEL OF ADMINISTRATION BETWEEN HERSELF AND THE VARIOUS BUREAU DIRECTORS. THIS REALIGNMENT WILL SCATTER RESPONSIBILITY FOR THE ESRD PROGRAM AMONG SEVERAL DIFFERENT BUREAUS, DIVISIONS AND BRANCHES. AS A RESULT OF THIS REALIGNMENT THERE WILL BE NO COORDINATION OF ACTIVITIES RELATED TO THIS UNIQUE ENTITLEMENT PROGRAM.

SINCE HER TESTIMONY BEFORE THE HOUSE COMMITTEE IN APRIL; DR. DAVIS HAS DEMONSTRATED NO INTEREST IN REVIEWING THE HISTORY OF NETWORKS OR IN AUTHORIZING ANY EVALUATION OF NETWORK PERFORMANCE.

NETWORKS WERE GIVEN RESPONSIBILITY FOR THE COLLECTION, VERIFICATION AND SUBMISSION OF ESRD DATA AS OF JANUARY 1 OF THIS YEAR. LOCAL SYSTEMS TO ACCOMPLISH THAT TASK ARE IN PLACE AND FUNCTIONING IN ALL NETWORKS; WITH MANY NETWORKS PRODUCING DETAILED INTERPRETATION AND EVALUATION OF THEIR DATA.

THE BELIEF OF THE ADMINISTRATION THAT THEY CAN SUCCEED IN THE ESTABLISHMENT OF A CENTRALIZED GOVERNMENT RUN DATA SYSTEM FOR ESRD IS CONTRARY TO THE THRUST OF THE PRESIDENT'S DOMESTIC PROGRAM AND THE RECENTLY ENACTED BUDGET RECONCILLIATION ACT.

THE FEDERAL GOVERNMENT SHOULD MAKE DECISIONS REGARDING THE DIRECTION AND FINANCING OF THE PROGRAM. DECISIONS AFFECTING MEDICAL CARE AND THE COST EFFECTIVE USE OF LIMITED MEDICAL RESOURCES CAN ONLY BE MADE AT THE GRASS ROOTS LEVEL.

THE ONLY ISSUES FOR CONGRESS AND THE ADMINISTRATION TO DECIDE ARE HOW TO BENEFIT FROM THE EXISTENCE OF NETWORKS, AND WHAT IS A REASONABLE PRICE TO PAY FOR THOSE BENEFITS. THE 1980 EXPENDITURE FOR ALL 32 NETWORKS COMBINED IS EQUAL TO LESS THAN 1/2 % OF THE COST OF MEDICAL CARE REIMBURSEMENT.

THE END STAGE RENAL DISEASE NETWORK PROGRAM IS NOT A FREE STANDING ACTIVITY WHICH CAN BE SIMPLY EXCISED FROM THE FEDERAL BUDGET. THE OPERATION OF ESRD NETWORKS AND THEIR FUNDING ARE INTEGRAL PARTS OF THE ADMINISTRATION OF THE ESRD ENTITLEMENT PROGRAM.

THIS CONGRESS HAS THE CHOICE OF SUPPORTING THE ONGOING DATA COLLECTION AND QUALITY ASSURANCE EFFORTS OF NETWORKS, OR AUTHORIZING FAR GREATER SUMS TO DUPLICATE THIS EFFORT ON A FEDERAL SCALE.

ESRD NETWORKS REPRESENT THE MOST COST EFFECTIVE USE OF PROGRAM ADMINISTRATION FUNDS AND ARE A PRIME EXAMPLE OF REDUCED FEDERAL REGULATION, REDUCED FEDERAL INTERVENTION AND ENHANCED LOCAL CONTROL OF MEDICAL RESOURCES AND QUALITY STANDARDS.

Mr. Chairman and members of the Committee:

Ever since the concept of ESRD Networks were first proposed in Federal Regulations in 1975, the relative merits of such community based consortia of patients and providers have been debated. Network regulations were finalized in June 1976. The 95th Congress formally recognized the necessity of funding Network organizations in the Renal Disease Amendments of 1978 (PL 95-292).

Networks have been funded and fully operational since 1978. In the period between then and now there have been three secretaries of HHS and four administrators of HCFA. The End Stage Renal Disease program has been under the successive administrative supervision of three bureaus and offices and has had no fewer than four program directors and directors of network administration. The Office of Special Programs, alone has had three Directors since the office was created two years ago. It has only been since the end of 1979 that the program has been administered by a team that has been supportive of the Network concept. While the concepts of management by objective and zero base budgetting have been successful in making the Networks cost effective in 1981; the administration persists in its refusal to examine either the purpose or the accomplishments of Networks.

On March 31 of this year, in an appearance before the House Ways and Means Sub-Committee on Health the present HCFA administrator, Dr. Carolyn Davis, testified in opposition to the continuance of federal funding for ESRD Networks. At that time she demonstrated a distressing lack of understanding as to the activities of Networks since 1978, and an even more distressing lack of awareness as to the specific accomplishments of Networks. This information is readily available; as it has been presented in full detail in Network

Annual Reports and supplemental documents. All documents are on file with the Office of End Stage Renal Disease.

Dr. Davis is currently proceeding with a realignment of HCFA, adding another level of administration between herself and the various bureau directors. This realignment will scatter responsibility for the ESRD program among several different Bureaus, Divisions and Branches. As a result of this realignment there will be no coordination of activities related to this unique entitlement program.

Since her testimony before the House Committee in April; Dr. Davis has demonstrated no interest in reviewing the history of Networks or in authorizing any evaluation of Network performance. Such a process of Network assessment was terminated, in its early stages, when the administration's proposed budget reductions were disclosed on March 10.

While this committee may not be desirous, at this time, of conducting its own evaluation of Network performance; a sufficient body of written materials exists to permit such an evaluation. The administration should be encouraged to make programmatic decisions and budgetary recommendations based upon an evaluation of cost effectiveness rather than based strictly upon program dollar allotments. Materials will be offered in support of this testimony. I request that acknowledgement of these documents be included as part of the official proceedings of this hearing.

The subject most often raised in any discussion of Networks is the collection, validation and interpretation of medical and programmatic data. It is oddly ironic and somewhat frustrating to have to defend the role of Networks in the area of data; as Networks were given responsibility for the collection, verification and submission of ESRD data as of January 1 of this year. Local systems to accomplish that task are in place and functioning in all Networks; with many Networks producing detailed interpretation and evaluation of their data.

A centralized ESRD Medical Information System which has existed on paper under four presidents and numerous HEW and HHS administrations can, to this day, produce no more complete, accurate and reliable data than that collected and submitted by the Networks. The belief of the administration that they can succeed in the establishment of a centralized government run data system for ESRD is contrary to the thrust of the President's domestic program and the recently enacted Budget Reconcilliation Act. The only reasonable way to collect complete and accurate program and medical outcome data is through a mechanism of local data consortia. Data collection can be justified and supported only as long as it results in improved medical care for patients and more cost effective administration of the program. Unverified data residing in a government owned computer benefits neither physicians, patients nor taxpayers. Changes in medical care administration, similarly, cannot be dictated in the form of government reimbursement guidelines.

Entitlement programs are designed to relieve the financial burdens on those without the means to pay for medical or other essential services. Attempting to alter provider behavior or enforce the collection of data through controls on reimbursement only serves to hold the medically indigent patient hostage in a bureaucratic game of cat and mouse.

Data is required by the administration and Congress to make decisions on this and other entitlement programs. The only reasonable and cost effective way to gather and verify that data is by supporting local groups of interested individuals who have a direct interest in the accuracy and use of the data, and who can best interpret their own findings. This is in no way to suggest that all ESRD program decisions be controlled locally. On the contrary, it is suggested that the federal government reserve for itself decisions regarding the direction and financing of the program. Decisions affecting medical care and the cost effective use of limited medical resources can only be made at the grass roots level. ESRD Networks provide the means for both cost effective data collection and appropriate use of that information in the allocation of resources and the administration of medical care.

The last subject I shall address is the overall role of the Network and the need for government funding for some aspects of Network operation.

While the word Network first appeared in the 1975 Interim Regulations; networks of chronic renal providers and networks of dialysis and transplanted patients predated those regulations and the 1972 legislation itself. It is those networks which are largely responsible for the enactment of Section 299I. The National Kidney Foundation, NAPHT and the Renal Physicians Association will continue whether or not Networks are funded. It is also a fact that Networks will in most areas continue to exist with or without federal support. The beneficial aspects of Networks in terms of data sharing, criteria setting and patient/provider interaction have become an integral part of the End Stage Renal Disease community.

The only issues for Congress and the administration to decide are how to benefit from the existence of Networks, and what is a reasonable price to pay for those benefits. The 1980 expenditure for all 32 Networks combined is equal to less than 1/2 % of the cost of medical care reimbursement.

The End Stage Renal Disease Network program is not a free standing activity which can be simply excised from the federal budget. The operation of ESRD Networks and their funding are integral parts of the administration of the ESRD entitlement program.

This Congress has the choice of supporting the ongoing data collection and quality assurance efforts of Networks, or authorizing far greater sums to duplicate this effort on a federal scale. The benefits to be gained by continuing to support the activities of ESRD Networks clearly justify the expenditure of 1/2 % of entitlement dollars. While ESRD Networks may represent the most cost effective use of program administration funds; they also represent the most vivid example of reduced federal regulation, reduced federal intervention and enhanced local control of medical resources and quality standards.

.END STAGE RENAL DISEASE NETWORK NO. 25, INC.

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HOWARD J. BOCHNEK
Executive Director

October 7, 1981

Hon. David Durenberger
Chairman
Sub-Committee on Health
Senate Finance Committee
353 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Durenberger,

On behalf of End Stage Renal Disease Network Coordinating Council No. 25 I wish to thank you for the opportunity to appear before the Health Sub-Committee on September 28.

As a follow-up to my testimony, and in response to questions which you raised; I am enclosing several documents for inclusion in the hearing record.

The November 21, 1980 and February 12, 1981 memos from the Acting Director of the Office of Special Programs, HCFA, delegates full responsibility for the input of data into the ESRD Medical Information System; to the thirty two ESRD Networks. These memos state the reasons for granting this responsibility to Networks, and enunciate the Department's expectations in this regard. These documents should further clarify the testimony of the HCFA Administrator, with regard to having "instituted a new data collection system" and the fact that HCFA data "has greatly improved over the past year".

The March 20, 1981 Position Paper is submitted in response to your questions regarding the need for ESRD program data.

/...

Hon. David Durenberger
October 7, 1981
page 2

In response to your inquiry regarding the working relationship between the present Administration and the Networks; I am enclosing correspondance from the Office of Special Programs and the Office of End Stage Renal Disease. A cooperative working relationship has existed between the Office of Special Programs and the Networks since early 1980. Several task forces, workgroups and committees, of physicians and Network staff, have worked closely with OSP and OESRD staff to redesign the ESRD Medical Information System and develop the blueprint for Networks represented by the August 21, 1981 transmittal.

As I stated at the hearing; the testimony of the Administrator of HCFA is not consistent with either facts or the actions of her staff. The staff of OSP and OESRD, in cooperation with Networks, has caused a focusing of Network priorities and activities; and have made Networks more accountable for the use of awarded funds.

You will be receiving, from Dr. Robert Guttman, a supplement to his testimony; which summarizes the activities and accomplishments of Networks to date. I referred to the preparation of this document in my testimony.

Again, I wish to thank the Sub-Committee and your staff for your concern and interest in all aspects of this program. If there is any further information which I can provide, I would be pleased to do so.

Sincerely,

Howard J. Bochnek
Executive Director

cc: Mr. Robert Lighthizer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration
Office of Special Programs
1848 Gwynn Oak Avenue
Baltimore, Maryland 21207

FEB 12 1981

TO: ALL ESRD NETWORK CHAIRPERSONS

On January 1, 1981, Networks began receiving directly from facilities the ESRD Patient History and Treatment Plan (HCFA-2742), ESRD Transplant Tissue Typing Information (HCFA-2745), and ESRD Death Notification (HCFA-2746). We would like to pass on to you some additional materials and information which will assist you in processing and submitting these Medical Information System (MIS) nonreimbursement forms.

Medical Information System Instruction Manual

Enclosed are a sufficient number of printed copies of the MIS Instruction Manual for distribution to the renal facilities in your Network. With the exception of the ESRD Facility Survey form (HCFA-2744) and its completion instructions, the material contained in this Instruction Manual is the same as that presented in the one accompanying my November 21, 1980 letter. You will notice that these copies are easier to read than the earlier ones. Revisions and additions to the Instruction Manual will be forwarded to you as such changes are made. If you need additional copies, please contact Ms. Mary O. Hill on (301) 597-3087.

Network Processing of MIS Forms

Enclosures 1, 2, and 3 contain the data elements requested on forms HCFA-2742, HCFA-2745, and HCFA-2746, respectively. We want to stress that all the information requested on these forms is essential for MIS purposes. Moreover, if certain data elements are missing or invalid, the Data Processing Center has the capability to obtain these elements from other sources. For the Network to build a viable data base, however, every data element should be present and valid. You will see by reviewing these Enclosures which data elements must be present and those which may be missing or invalid when the forms are submitted to the Data Processing Center.

Enclosure 4 contains information on health insurance cards, health insurance claim numbers, and Railroad Retirement Board (RRB) claim numbers. This material was extracted from Part A Intermediary Manual section 3500, "Admission and Query Procedures," pages 99.2 through 100.1. Enclosure 4 will enable you to ensure the validity of the claim numbers appearing on the MIS forms.

Transmittal Sheet and Mailing of Forms

You have already received copies of the MIS Forms Transmittal Sheet (Enclosure 5). We would appreciate your utilizing this Transmittal Sheet when submitting your forms to the Data Processing Center. Once the forms are received by the Data Processing Center, they will be annotated (signed and dated) and returned to you for your records.

As we mentioned in my November 21, 1980 letter, all forms must be submitted to the Data Processing Center by the 15th of the month for forms received the previous month (e.g., forms dated January 1981 should be submitted before February 15, 1981). All forms are to be mailed via standard postal service.

Data Processing Center/Network Forms Coordinators

If you wish to contact the Data Processing Center, you may do so by telephoning Mrs. Hazel Tillman on (301) 594-3988 or Mr. Bob Bott on (301) 594-3989. Please restrict your calls to the Data Processing Center to matters pertaining to the technical completion of items on the forms, data entered on the Transmittal Sheet, and/or Network receipt/nonreceipt of annotated Transmittal Sheets. Conversely, we are requesting that you designate someone within your Network to whom questions on individual forms may be directed (by telephone) by staff of the Data Processing Center. Please provide us with the individual's name and telephone number. In addition, if you would prefer these calls be made only on certain days and/or at certain times during the day, please indicate this also. This information should be telephoned at your earliest convenience to Pat Peyton, (301) 597-3089, and you should continue to direct any other questions on the flow of the MIS forms to her.

Sincerely yours,

Edward L Kelly

Edward L. Kelly
Acting Director

Enclosures

cc:
Network Executive Directors
Regional Office ESRD Network Coordinators

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION
BALTIMORE, MARYLAND 21235

REFER TO

NOV 21 [illegible]

TO: ALL ESRD NETWORK CHAIRPERSONS

As we discussed at the recent data workshops in Baltimore and Denver, the national End-Stage Renal Disease Medical Information System (ESRD MIS) has been plagued with high nonreporting rates by ESRD facilities of the nonreimbursement forms (patient history, transplant, and death forms). In order to increase compliance in submitting forms and to validate the data received, we are requiring, beginning January 1, 1981, that the following nonreimbursement ESRD MIS forms flow from the ESRD facilities directly to the Network Coordinating Council (NCC) office:

HCFA-2742 - ESRD Patient History and Treatment Plan

HCFA-2745 - ESRD Transplant Tissue Typing Information (formerly HCFA-600-1)

HCFA-2746 - ESRD Death Notification (formerly HCFA-600-2)

This procedure transfers the following responsibilities from HCFA to the NCCs:

(1) monitoring the compliance of facility submission of the nonreimbursement MIS forms described above;

(2) verifying the validity of the data contained on these forms, including developing procedures for making corrections in such data;

(3) establishing a control system to track the numbers and types of forms received, and dates of receipt;

(4) acting as liaison for forms distribution (optional);

(5) training facility personnel on MIS forms;

(6) submitting all processable forms to the MIS Data Processing Center on a timely basis (no later than the 15th of the month following the month the forms were received in your office)

(7) developing procedures for privacy requirements regarding patient specific data contained on these forms; and

(8) providing technical assistance to HCFA in suggesting innovations to the data flow.

As you are already aware, the Federal Register dated June 3, 1976, section 405.2133, requires ESRD facilities to furnish "...data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant in program administration..." Any facility that fails to complete the required MIS forms is not in compliance with the conditions of participation in the Medicare program. If you encounter an ESRD facility that does not submit the MIS forms, please document your actions to attempt to get the data. If, after 60 days, you are unable to obtain the appropriate MIS forms, please send me the facility's ESRD provider number, the administrator's name, and the facility's address. Federal actions will then be taken to compel the facility to comply with the conditions of participation.

We also mentioned at the data workshops that two forms will become obsolete in early 1981. (This action will not affect the flow of MIS forms at this time.) Those two forms are as follows:

HCFA-2742 - HCFA Patient History and Treatment Plan This form will be replaced by the revised HCFA-2728, Chronic Renal Disease Medical Evidence. When the revised HCFA-2728 is printed and available in early 1981, facilities will submit the original to the local social security office and, at the same time, forward the MIS and Network copies to your office. Thus, when the revised HCFA-2728 is available, the HCFA-2742 will no longer be used.

HCFA-2743 - ESRD Outpatient Dialysis Service Information. To reduce the reporting burden on facilities, the HCFA-2743 will become obsolete on January 1, 1981, and certain data that would have been entered on the HCFA-2743 will instead be entered on the HCFA-1483, Provider Billing for Medical and Other Health Services. New ESRD codes and completion instructions appear in the Intermediary Manual (HCFA--Pub. 13-3), the Renal Dialysis Facility Manual (HCFA--Pub. 29), and Hospital Manual (HCFA--Pub. 10).

To assist ESRD facilities in preparing and submitting the nonreimbursement forms, we have enclosed a copy of the recently revised MIS Instruction Manual. You may wish to duplicate this for the facilities in your Network until such time as additional copies are available from this office. Also enclosed is a model letter to ESRD facilities announcing these changes in ESRD MIS forms submission. Perhaps this letter, possibly tailored to suit the needs of your individual Network, can be used to notify your facilities of these new procedures.

We appreciate the enthusiasm and cooperation you have expressed in having these forms flow through your office, and feel this will result in the MIS receiving valid and timely data. If you have questions on this new procedure, please call Pat Peyton at (301) 597-3089.

Sincerely yours,

Edward L Kelly

Edward L. Kelly
Acting Director
Office of Special Programs

Enclosures 2

cc: Network Executive Directors
Regional Office Network Coordinators

PRESERVATION OF A NATIONAL END STAGE RENAL DISEASE DATA BASE

POSITION PAPER

MARCH 20, 1981

Jan Anderson	Network 7	Minnesota
Howard Bochnek	Network 25	New York Metro
Charlene Brax	Network 4	So. California So. Nevada
Nancy Davison	Network 21	South Carolina
William Fox	Network 17	Kentucky So.W. Ohio
Judith Kari	Network 23	D.C. Metro
Stephen Ketchum	Network 15	Illinois
Shirley Melton	Network 9	Missouri Kansas
Spero Moutsatsos	Network 19	Florida
Steve Pitts	Network 18	Tennessee Mississippi Alabama

MAINTAINING A VITAL ESRD DATA SYSTEM

1.0 Introduction

Essential to the effective and economical operation of the End Stage Renal Disease (ESRD) Program, at any level, is the availability of reliable, valid, and timely data relating to the care of patients with ESRD. Such a sound data base represents a critical and important management tool in achieving improvements in patient care and in the planned, orderly and controlled growth, and fiscally responsible distribution of ESRD resources. With reliable and valid data, the U.S. Congress and the ESRD program managers can answer and continue to answer the following critical questions:

- What is the total number of patients who are on chronic maintenance dialysis, on home dialysis, and off dialysis with a functioning renal transplant?
- What is the patient flow among the various treatment modalities during the reporting period, e.g., new patients, patients transplanted, patients moving to and from home dialysis, and transplant patients returning to dialysis?
- What are the key morbidity and mortality measures for dialysis and transplant patients?
- How many transplants are performed? How many are successful?
- What are the age, sex, and primary disease distributions for dialysis and transplant patients?
- What percent of ESRD patients are candidates for transplant and home dialysis?
- What were the most frequent reasons requiring admissions to a hospital for patients currently under treatment?

- o How many patients died while on dialysis or with a functioning transplant?

Inaddition the Congress and administration require valid national data to evaluate a decision to establish and continue a national health program for a single disease and support future decision regarding broader health care provision.

Recognizing the vital importance of the collection and analysis of data as a mechanism for analyzing cost-effectiveness, a national End Stage Renal Disease Medical Information System (ESRD-MIS) was established. From the beginning, the national ESRD-MIS has been plagued with problems such as low data response rates by ESRD facilities as well as major in-house operational difficulties. For example, in 1978, the Acting Director of the Division of Information Systems and Beneficiary Entitlement stated that, nationally, 53 percent of all patient histories were unreported, 42 percent of all transplant information forms were unreported, and 68 percent of all death notification forms were not received. These figures further emphasize the need for Network participation in the information gathering process.

In order to improve the reporting and the accuracy of national ESRD-MIS data, the Office of Special Programs (OSP) on November 21, 1980, assigned to the ESRD Networks:

- o Monitoring the compliance of facility submission of the non-reimbursement MIS forms;
- o Verifying the validity of the data contained on these forms, including developing procedures for making corrections on such data;

- Establishing a control system to track the numbers and types of forms received, and the dates of receipt;
- Acting as liaison with ESRD facilities for form distribution;
- Training facility personnel on MIS forms;
- Submitting all processable forms to the MIS Data Processing Center on a timely basis;
- Developing procedures for privacy requirements regarding patient-specific data contained on these forms; and
- Providing technical assistance to HCFA in suggesting innovations in the data flow process.

Networks assumed these responsibilities January 1, 1981, in accordance with HCFA directives. Furthermore, through intermediary manuals, HCFA instructed ESRD facilities to submit data to the Networks. This transfer of responsibility was in recognition of: (1) the failure of a national system to collect such significant data and (2) the demonstrated proficiency of the Networks in collecting and editing 1980 data generated by ESRD facilities within each Network's geographic area. An indication of the success of this change is the 100 percent compliance achieved in 1980 Facility Survey reporting.

2.0 Problem Statement

The Administration has recommended elimination of Federal support for HSAs and PSROs. The same proposal also includes elimination of ESRD Network Coordinating Councils, based on the misconception that they were established primarily to serve as advisors to health planning agencies and PSROs. In fact, Public Law 95-292 designated Networks to advise the Secretary of the Department of Health and Human Services regarding Network goals to achieve national objectives for promoting home dialysis and transplantation and reporting to the Secretary on facility performance and cooperation toward the achievement of Network goals. The role of Networks in coordinating and submitting ESRD patient and facility data to the national Medical Information System grew out of these basic statutory responsibilities. If an appropriation is not made to retain local capabilities to support the MIS, the national data system will disintegrate to its status of one year ago — when the system was unable to meet the needs of Congress or the Administration for data to evaluate program effectiveness and make plans for future ESRD Program development.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration
Office of Special Programs
1848 Gwynn Oak Avenue
Baltimore, Maryland 21207

TO: ALL ESRD NETWORK CHAIRPERSONS AUG 21 1981

Network Executive Directors and OESRD staff recently met in Minneapolis to discuss the format and requirements for the objectives to be submitted in Networks' 1982 budget applications. Enclosure A, "Goals and Objectives Format 1982" represents the final instructions to Networks for the preparation of 1982 objectives. We hope that your Network Coordinating Council and its committees will shortly review this document and begin formulating the 1982 objectives. As you know, all 1982 Network funding applications are due by October 15, 1981.

We want to emphasize that the enclosed objectives format is a consensus document, with contributions from physicians, Network staff, and OESRD staff. It represents an attempt to bring greater conformity and accountability to the Network objective setting process. We feel that this format provides both a practical approach for Networks to fulfill their statutory and regulatory responsibilities as well as a framework within which Networks can pursue local initiatives related to these mandated responsibilities.

Please note that enclosed objectives format is designed to supplement rather than replace Section IV, "Network Council Objectives," of the funding application package. Enclosure A specifically identifies the primary objectives a Network should pursue and the appropriate measures of performance for these objectives. Networks are still required to describe fully the anticipated methodology for achieving these objectives, as outlined in the funding application package.

For your convenience, we have also enclosed the final versions of the data and funding policies for 1982. Enclosure B, "Data Addendum" contains the requirements for Networks' 1982 data proposal submissions. Enclosure C, "ESRD Network Funding Policies and Procedures," contains the financial policies Networks are to apply in preparing 1982 budgets. These policies supplement the cost principles outlined in OMB Circular No. A-122 and Title 45 Part 74, copies of which have previously been distributed to all Networks.

Page - All ESRD Network Chairpersons

Please contact your Project Officer if you have questions regarding any of the enclosed documents. Thank you for your continuing cooperation in working to achieve the goals of the ESRD program.

Sincerely yours,

Spencer Schron
Director
Office of End-Stage Renal Disease

Enclosures

cc:
Regional Office ESRD Network Coordinator

Enclosure A

NETWORK COORDINATING COUNCIL
GOALS AND OBJECTIVES FORMAT
1982

I. MEDICAL REVIEW

A. GOAL: Increase the use of home dialysis to the maximum practical number of ESRD patients who are medically, socially, and psychologically suitable candidates for such treatment. Social Security Act, Section 1881(c)(6)

1. OBJECTIVE: Achieve the optimal number of home patients as a percentage of total "dialysis patients receiving care" at the end of the following survey periods:

July 1, 1981-December 31, 1981
January 1, 1982-June 30, 1982
July 1, 1982-December 31, 1982

Measure of Performance: Total home patients (Fields 21 + 22 + 23) divided by the total number of dialysis patients receiving care at the end of survey period (Field 24).

Supplementary (optional) measure of performance: Total self-care (Fields 16 + 17 + 21 + 22 + 23) divided by the total number of dialysis patients receiving care at end of survey period (Field 24).

Explanation: Predict the numbers which will appear in the facility survey for the survey periods above.

a. SUB-OBJECTIVE: The proportion of total number home trained patients divided by the total number of "started for first time ever" patients times 100 for 1982 will be __________%.

Measure of Performance: Total home self-dialysis patients completing training (Fields 29 + 31 + 33) divided by the total "started for first time ever" patients (Fields 04A + 04B)

Supplementary (optional) measures of performance:

- Total "self-care dialysis patients completing training" (Fields 29 + 30 + 31 + 32 + 33) divided by the total "started for first time ever" (Fields 04A + 04B).
- Total shifted status (home to in-unit) (Field 28B) divided by the total number of home patients (Fields 21 + 22 + 23).

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B. GOAL: Increase the use of renal transplantation to the maximum practical number of ESRD patients who are medically, socially, and psychologically suitable candidates for such treatment. Social Security Act, Section 1881(c)(6).

1. OBJECTIVE: Achieve optimal number of dialysis patients receiving transplant as a percentage of total "patients receiving care" at the end of the following survey periods:

   July 1, 1981-December 31, 1981
   January 1, 1982-June 30, 1982
   July 1, 1982-December 31, 1982

   Measure of Performance: Total "losses during survey period--receiving transplant" (Fields 10A + 10B) divided by: "patients receiving care at beginning of survey period" (Field 03) PLUS "patients started for first time ever" (Fields 04A + 04B) PLUS "restarted" (Fields 05A + 05B) PLUS "returned after transplantation" (Fields 07A + 07B).

   Supplementary (optional) measures of performance:

   - Total "transplants performed" (total of Field 56 for all transplant centers in the Network) divided by: "patients receiving care at beginning of survey period" (Field 03) PLUS "patients started for first time ever" (Fields 04A + 04B) PLUS "restarted" (Fields 05A +05B) PLUS "returned after transplantation" (Fields 07A + 07B).

   - Total number of transplants performed.

   - Total number of patients with a functioning graft.

   Report transplant procedures by:

   - Number Medicare beneficiaries
   - Number non-Medicare beneficiaries
   - Number non U.S. residents

   a. SUB-OBJECTIVE: Achieve the optimal number of cadaver kidneys available for transplantation from the baseline survey period (January 1-June 30, 1981) as measured at the end of the following survey periods:

      July 1, 1981-December 31, 1981
      January 1, 1982-June 30, 1982
      July 1, 1982-December 31, 1982

   b. SUB-OBJECTIVE: Examine strengths and weaknesses in systems of organ procurement, exchange, and usage and recommend changes where appropriate.

2. OBJECTIVE: Collect and analyze patient and graft survival data, and recommend changes where appropriate. (CFR 405.2113e)

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C. GOAL: Assure the effectiveness of patient long-term programs to assess the appropriateness of patients for the prosposed treatment procedures. (CFR 405.2113(d)(1))

1. OBJECTIVE: Establish and apply criteria for determining potential home dialysis and transplant candidates.

   Suggested activities:

   - o Characterize (by dialysis history, medical and pre-morbid status, social status, and source of kidney) patients receiving transplanted kidneys or undergoing home dialysis.
   - o Collect data which describe the morbidity and mortality of recipients.
   - o Identify the (number of) patients not scheduled for transplantation or home training (i.e., who are to be maintained on dialysis treatment) who share these characteristics.
   - o Provide these comparative data to facilities to aid in treatment and recommendations.

2. OBJECTIVE: Determine the extent to which individual facilities are involving patients and appropriate staff in the development of long-term programs and the specific components of the long-term program which are included as a part of the patient's medical record. (CFR 405.2137(a)(1))

   Suggested activities:

   - o Survey facilities regarding the components, manner of preparation and frequency of review of patient long-term programs.
   - o Review a sample of patient records.
   - o Survey nurses, social workers, and nutritionists to determine their current role in the preparation of long-term programs.
   - o Survey home dialysis training programs and transplant centers to determine the extent of home-training physician and transplant surgeon involvement in the preparation and/or review of long-term programs from other facilities.
   - o Review the content of back-up, referral, or arrangement agreements between ESRD facilities to determine the role of training physicians and transplant surgeons.

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D. GOAL: Establish criteria and standards for and measure the quality and appropriateness of patient care and provide results of such efforts to member institutions and the Secretary. Social Security Act, Section 1881(c)(1)(A) and Section 1881(c)(2)(B).

1. OBJECTIVE: Determine morbidity rates for a specific critical area within the Network.

    a. SUB-OBJECTIVE: Develop useful and uniform measures of morbidity for that critical area using available data within Network areas.

    Mandatory activities for achieving OBJECTIVE 1:

    (1) Evaluate a critical area of patient morbidity and study it intensively.

    (2) Define data set, establish quantitative criteria and standards, and begin to collect baseline data to determine patterns of morbidity.

2. OBJECTIVE: Determine ESRD patient mortality rates for the Network area.

    a. SUB-OBJECTIVE: Develop useful and uniform measures of mortality using available data within Network areas.

    Mandatory activity for achieving OBJECTIVE 2:

    (1) Develop age-specific, race-specific, and renal diagnosis-specific mortality rates.

    Supplementary (optional) activity:

    - o Develop useful and uniform measures of predialysis status (medical, social, and educational, etc.).

II. HEALTH PLANNING

A. GOAL: Compliance with the Social Security Act: to recommend "with respect to the need for additional or alternative services or facilities in the Network in order to meet the Network goals, including self-dialysis training, transplantation, and organ procurement facilities". Social Security Act, Section 1881(c)(2)(E) and Section 1831(c)(3)

1. OBJECTIVE: Develop the capability to collect and analyze data with respect to the need for additional or alternative services or facilities in the Network and provide data to interested parties.

    a. SUB-OBJECTIVE: Develop local incidence and prevalence data.

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b. SUB-OBJECTIVE: Develop local treatment capacity and utilization data.

III. OTHER PROGRAM ACTIVITIES

A. GOAL: Encourage successful rehabilitation of patients. Social Security Act, Section 1881(c)(1)(B) and 1881(c)(2)(A).

Mandatory activities for achieving GOAL A:

(1) Define "successful rehabilitaton" in the Network.

(2) Survey Network facilities to identify what each is doing to assure the rehabilitation of its patients.

(3) Assure that an information resource is available to assist patients in achieving higher levels of rehabilitation.

(4) Examine available data related to rehabilitation.

B. GOAL: Develop a means for effective patient representation in NCCs and for the identification of patient concerns. Social Security Act, Section 1881(c)(1)(B) and 1881(c)(2)(A).

Mandatory activities for achieving GOAL B:

(1) Develop a mechanism for improving patients' participation in the activities of the NCC.

(2) Document existence of or create a Network patient grievance mechanism.

IV. DATA MANAGEMENT

A. GOAL: Promote the exchange of data and information necessary to assure effective and efficient administration of ESRD benefits through support of national ESRD Medical Information System. Social Security Act, Section 1881(c)(1)(A).

1. OBJECTIVE: Achieve a level of 95% on submittal of the data required by HCFA, i.e., compliance and accuracy. The objective should be reached by December 1982.

Mandatory activities:

(1) Collect and forward validated nonreimbursement data forms to HCFA; HCFA-2728 (Medical Evidence), HCFA-2745 (Transplant), HCFA-2746 (Death).

(a) Collect, control, and review for omissions, inconsistencies, and inaccuracies.

(b) Obtain corrected data from facility/physician.

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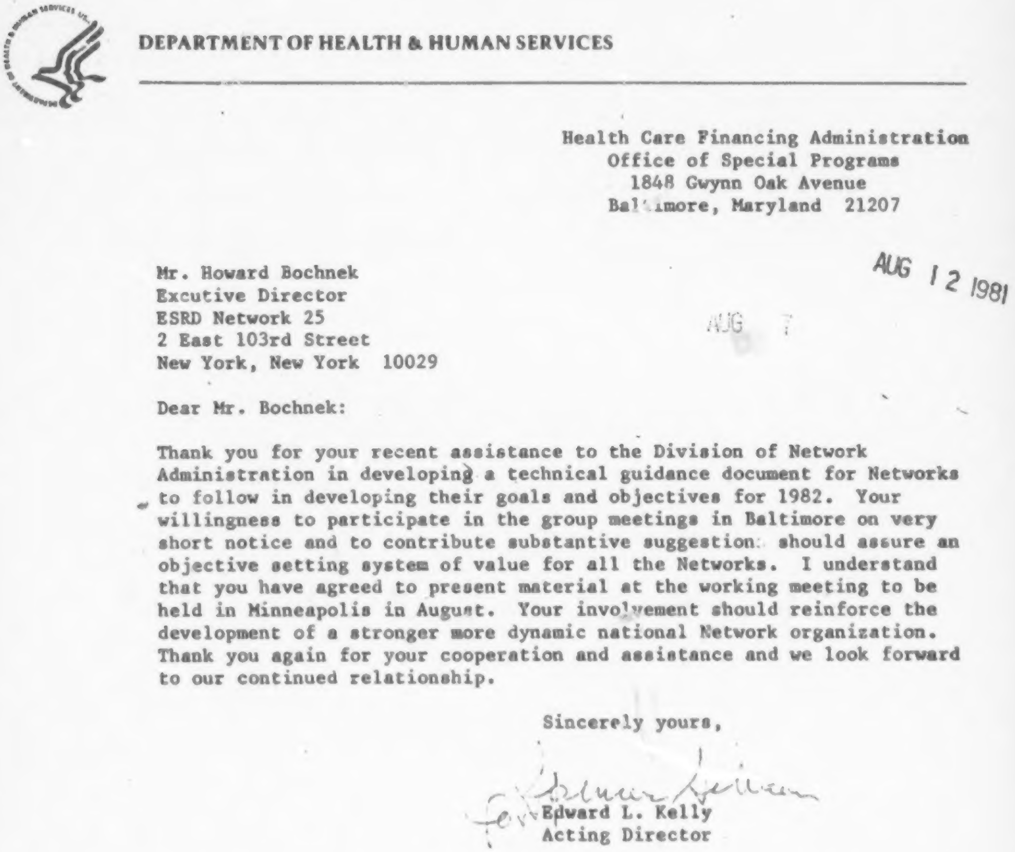
(c) Provide for a systematic alert for failure by a facility to submit the required forms (1) on time and (2) reasonably accurate. This should include cross check between the Facility Survey and the Census data...you should have received a HCFA-2745 for each transplant reported; similarly a HCFA-2746 for deaths reported, and a HCFA-2728 for new starts.

(d) Provide training for facilities which have data compliance or quality problems.

(e) Follow up facilities/physicians to correct data problems identified by HCFA. Document efforts to obtain required data so that, if HCFA must take additional steps, there will be sufficient ground work.

2. Complete and validate the semi-annual patient census reports and facility survey forms.

BEST COPY AVAILABLE



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration
Office of Special Programs
1848 Gwynn Oak Avenue
Baltimore, Maryland 21207

AUG 12 1981

Mr. Howard Bochnek
Excutive Director
ESRD Network 25
2 East 103rd Street
New York, New York 10029

AUG 7

Dear Mr. Bochnek:

Thank you for your recent assistance to the Division of Network Administration in developing a technical guidance document for Networks to follow in developing their goals and objectives for 1982. Your willingness to participate in the group meetings in Baltimore on very short notice and to contribute substantive suggestions should assure an objective setting system of value for all the Networks. I understand that you have agreed to present material at the working meeting to be held in Minneapolis in August. Your involvement should reinforce the development of a stronger more dynamic national Network organization. Thank you again for your cooperation and assistance and we look forward to our continued relationship.

Sincerely yours,

for Edward L. Kelly
Acting Director

Senator DURENBERGER. Let me ask a question of Dr. Gutman. Is the National Forum of ESRD Networks a national association of some kind?

Dr. GUTMAN. It is a loose confederation of the local people who share problems and have elected a president.

Senator DURENBERGER. All right. What kind of a dialog has developed between the networks and the Administrator of HCFA?

Dr. GUTMAN. I cannot answer that question very well. May I call on the president of the organization to answer it? I just cannot give a substantive answer to it.

Senator DURENBERGER. Well, let me skip that question and perhaps come back to it if it is important.

I was impressed by Dr. Davis' statement because, in part, it showed that she was knowledgeable about what was going on, not only in HHS and HCFA but in other departments. It showed a commitment to integrating some of these processes. Yet, the bottom line is a recommendation to abolish the networks.

The administration has suggested that we phase out HSA's PSRO's, and now networks. Has the current administration evaluated the networks from the same perspective as HSA's and PSRO's, or has it engaged in a dialog with you indicating a special approach to the network concept?

Dr. GUTMAN. Regardless of discussions that might have been held, there is a difference in understanding that derives, at least in part, from the original expectation that the networks would do the kind of work that the PSRO's would do.

There are some big differences between the required activities of the PSRO's and the necessary activities of the networks.

The PSRO's are busy reviewing the duration of hospitalization of people with a relatively short-term illness. The networks are busy trying to bring together a group of people to plan for the future care of people outside the hospital with a long-term illness.

There was originally a hope—in my opinion, a naive hope—that the process to reduce costs for these hospitalized patients and improved quality of care for the long-term-ill patients could be the same.

In the PSRO system, it was review of charts. It was hoped that the medical review boards would carry out the same process, mechanically. So that when Dr. Davis looks at the activities of the medical review boards who tried, as Dr. Pfaff indicated at the outset, to fit this model, all that we wound up with were some frankly fairly perfunctory reports about some things that were going on in the dialysis units. A few very useful things came out of it. Some review of hepatitis control measures did, in fact, have a direct effect in many units, including my own. We felt the peer pressure, and we did change our policies, and we did see a substantial reduction in hepatitis.

That keeps coming up because it is one of the few areas that does fit the PSRO model.

What we are saying now is that regardless of the expectations at the outset, what we have learned is that groups our size, operating roughly as we do with a lot of volunteer physician time, are learning, passing that information back to the provider's information, and that that process is a healthier and more effective process than the traditional PSRO activities.

We never saw ourselves as a PSRO. And we agree that the PSRO function, even for in-patients, is a little bit hard to accomplish, and it is especially true for the kind of problems that we face.

Mr. **Bochnek**. Mr. Chairman, I would like to try to respond to that question directly.

Senator **Durenberger**. All right.

Mr. **Bochnek**. Within HCFA, the Office of Special Programs and the Office of End Stage Renal Disease has been extremely cooperative in working with the networks, particularly in the past 18 months, and very intensively during the past 6 months. The staff of the Office of Special Programs, particularly within the Office of End Stage Renal Disease, has worked very closely with network executive directors, network chairmen, groups and committees of both together; to come up with a coordinated program and plan for what networks will do in 1982. That is a structured set of goals and objectives, with a means for evaluating network performance and for gaging future network funding.

True, this should have been done 4 years ago, and this is something which we had advocated doing 4 years ago. But during the past 6 months, within HCFA, this has been done as a cooperative effort with the networks.

Unfortunately, the testimony from the Administrator earlier this afternoon did not reflect any of that activity. And, frankly, for me, this is my ninth trip to the Washington-Baltimore area this year—to discuss such issues with the administration, I find it very puzzling that that cooperative effort and that plan for 1982 and that plan for network evaluation just did not surface in the Administrator's testimony today.

Senator **Durenberger**. Let me ask Dr. Lyons and Dr. Pfaff about your experience with home dialysis in your two networks. Dr. Lyons, in your testimony you mentioned that about 25 percent of all new patients in your network are trained for home dialysis. And in the written statement you mention 120 percent, and so forth.

Dr. **Pfaff**. 120-percent increase.

Senator **Durenberger**. What percentage of patients actually initiate home dialysis, and how many continue with home dialysis for 12 months or more? Could each of you respond to that?

Dr. **Lyons**. The 25-percent figure is the figure for patients who actually complete the training program. So those are people who either go home, or if they are going to be self-care in center, initiate self-care dialysis. Almost all of them go home.

At our last calculation, and this is rough, the dropout rate is about 4 percent per year. So that almost everyone who goes home stays home. That is 4 percent of the 25 percent. It doesn't get down to 21 percent, OK? So almost everyone that we send home goes home.

I think it is important to identify that a large proportion of the increase is, although not all of it, is because of CAPD. But then we would have to ask what role the intensive network educational program for the physicians, nurses and patients in our area have to do with that kind of dramatic increase.

Senator **Durenberger**. All right. Thank you.

Dr. **Pfaff**. We have got a more complex matter. We have an area of the State, the northern third, which is very rural, and the distances and the geographic factors that were alluded to before come into play. In the southern third of the State, which is densely populated, there is a dialysis unit at every stop light to beat that density, then access to dialysis is relatively easy.

There is a difference in the philosophy among physicians in the State.

Did I answer your question? I really cannot with accuracy as to the percentage of incoming patients. The patients that go on home dialysis do so for many, many reasons. An increasing number, as Pat Lyons described, are in CAPD. There are some particular reasons for that. We do a better job with keeping kids in school with CAPD, for example, in our own institution where we see a lot of children.

I cannot give you an effective target rate. I think it has to be corrected for all of the risk factors that we have been looking at. Diabetes is a risk factor in terms of hemodialysis, transplantation and CAPD. The percentage of diabetics in a population; the age of a population; the incidence of divorce in a population. It is going to be a lot more complex than a single answer would give you.

We have increased our rate of training from about 4 percent of the total population to about 8 percent. As to incoming patients, that would be of the order of probably 16 or 18 percent. And it is incoming patients in the main who choose one modality versus the other. Most of the transplant patients, for example, are likely to come out of a new patient pool, not an old patient pool. There are exceptions to that as well as you have heard them from the patient population earlier today.

Senator **Durenberger**. At various times during the afternoon we have addressed rather dramatic changes in the reimbursement process. As I listened to Mr. Bochnek outline three or four things that he expected from government, I thought that we only have one responsibility and that is in the area of income security. If we did that one well, all these other things might fall in place. But we have in existence a system at which we reimburse providers directly rather than individuals that are involved.

Do you think that networks would do better as a rule if we changed the reimbursement process and actually made the financing available to the individual involved rather than reimbursing the provider or institution? Would there then be a greater demand for alternative kinds of service?

Dr. **Pfaff**. Are you speaking about the voucher system again?

Senator **Durenberger**. If that's what you want to call it.

Dr. **Pfaff**. Basically, it negates quality of care as a prime standard. And the mode of delivering quality care to an individual has to be or may be very different for one person as opposed to another, and may be a lot more expensive. And so if you give a man who is going to be terribly sick, let's say, his $50,000, what are you going to do at the end of the year when he has just set new standards for the cost of dialyzing a patient?

Senator **Durenberger**. Thank you.

Any other comments?

Dr. **Gutman**. I think it is quite unpredictable the effect it would have on the frequency of home dialysis and the role of the networks. But I would like to emphasize something that has already been alluded to.

We saw six very well rehabilitated patients here speaking today. Such patients would benefit from a system without question. Our data and that of other people suggest that in many respects they do not represent the majority of patients on maintenance dialysis with respect to educational achievement, sophistication, workability and so forth. And the notion that patients would actually have an independent access to this information is I think naive.

It would still in one way or another come through the providers.

There is at least one country that I know of that does have sort of open market dialysis. I visited Germany at the CAPD symposium earlier this summer and was informed that they do have such a system, and their average cost per dialysis today and as far as I know, the same cost to the providers, is about the same, about $320 per dialysis.

Mr. **Bochnek**. Just briefly, the role of the network has never been anywhere in the area of financial reimbursement or reimbursement issue. So I don't think that that would have any impact on networks.

The only appropriate role for the network is to make sure that the patients have the option to be in the most appropriate modality of care for the individual patient. If we do that job right, then I think we will find that patients who are most suitable for transplantation will be transplanted, and patients who are most suitable for home dialysis will end up on home dialysis. And if there is some evidence that home dialysis in some areas might be just as expensive or even slightly more expensive than in center dialysis, I think our attitude has to be, so be it.

The only concern of the network must be to go straight ahead in terms of assuring the best quality of care for patients, the highest level of rehabilitation for the patients, and the assurance that each patient has been presented with the full choice of medical therapies available.

Senator **Durenberger**. I think you have answered my question affirmatively that if these people had some combination of their own resources and medicare-base resources, they would come beating a path to your door to find out where they could get the most bang for their buck. Would that not be the case?

Mr. **Bochnek**. Probably they would. The appropriateness of the network in that role is something that a lot of us would have to start thinking about very carefully.

Senator **Durenberger**. All right. Thank you all very much, and thank you especially for your patience.

This part of the hearing will be adjourned. There will be another later in the month. Thank you.

[Whereupon, at 5:48 p.m., the hearing was adjourned.]

[By direction of the chairman the following communications were made a part of the hearing record:]

Bio-Medical Applications of Alexandria, Inc.
405 THIRD STREET
ALEXANDRIA, LOUISIANA 71301
PHONE (318) 487-1055

October 6, 1981

Honorable Dave Durenberger, Chairman
Subcommittee on Health
Committee on Finance
United States Senate
2227 Dirksen Senate Office Building
Washington, D. C. 20510

Re: Hearings on End Stage Renal Disease Program by Senate Finance Sub-committee on Health. Hearings began on Monday, Sept. 28.

Dear Chairman Durenberger:

I am writing to you as a member of the Executive Committee, End Stage Renal Disease Network 12 Coordinating Council, as well as a provider of primary care for end stage renal disease patients.

Apparently, these hearings will contain active discussions concerning the future organization under which the end stage renal disease program will be administered. No doubt the removal of federal regulations as administered through Health Care Financing Administration and the ESRD Networks, would affect adversely the cost effectiveness and the quality of medical care of this program. If the states are allowed to determine the need for facilities and the federal government continues to pay the cost of the end stage renal disease program through Medicare, we will see the advent of innumerable dialysis units each having a small number of patients.

This combination of state certification and federal reimbursement will lead to deliverance of care in a cost inefficient and medically inefficient manner.

The bulk of this statement will touch on several aspects of planned testimony. These will include: (1) the impact the certificate of need process has on patients, providers, and cost (2) the role of the networks (present and future) (3) patient access to the facilities, treatment modalities, and physicians.

As stated earlier, if the states are allowed to determine need and funding remains with the federal government, the states will have little or no incentive to insist on cost efficient delivery of care. Currently the federal government has a system in operation with comprehensive review of applications at the network level, providing the most knowledgeable and critical review. However, almost without exception applications for new dialysis centers are approved by all state agencies and by the network regional offices. (See chart p.3) It is my contention that review of these applications at the federal level by the local network executive committee helps to contain cost.

If dialysis units are allowed to multiply uncontrollably, you will see beyond any doubt the following adverse results.

1981 APPLICATIONS FOR REVIEW

END STAGE RENAL DISEASE NETWORK 12

APPLICANT	DATE RECEIVED	DATE REVIEWED	RULINGS				
			NETWORK	HSA	LICENSURE	SHPDA	REGIONAL OFFICE
St Patrick Expansion	1/21/81	3/19/81	A	A	A	A	A
Natchitoches Dialysis Facility	3/27/81	6/11/81	D	A	A	A	A
St. Tammany Parish Exp.	4/7/81	6/11/81	A	A	A	A	A
BMA of Metairie Exp.	4/27/81	6/11/81	A	A	A	A	A
West Jefferson Renal Ctr.	4/10/81	6/11/81	D	D	A	A	A
West Jefferson Dialysis Ctr.	5/20/81	6/11/81	D	A	A	A	A
New Iberia Art. Kidney Ctr.	5/15/81	6/11/81	A	A	A	A	A
BMA of Marrero	5/15/81	6/11/81	D	D	A	A	A
St. Mary Parish Dialysis	12/80	1/22/81	D	A	A	A	A

1. Small units will become cost inefficient leading to an increase in political pressure by both patients and providers to increase the allowable screen paid for dialysis.
2. To improve cost efficiency, small dialysis units will attempt to become large dialysis units. This will be accomplished by failure to refer patients into more cost efficient and often more medically effective forms of therapy, and by referring patients to dialysis earlier in the stage of their disease, or by referring very questionable patients to dialysis.
3. Without controls as stated above and a marked increase in dialysis patients, the escallation in the cost of the program will eventually lead to the establishment of a ceiling on the money available for end stage renal disease patients. This will result in a return to the unfortunate and uncomfortable situation which existed early in dialysis treatment, in which not all patients who need therapy can be treated, thus leading to the establishment of the dreaded "life and death committees".
4. Establishment of multiple small dialysis units, particularly in outlying areas without qualified resident physicians i.e. nephrologists, will lead to a decline in the medical treatment of these patients, a decrease in the number of treatment modalities offered, and most importantly, limited access to qualified physicians for this therapy. This will lead to the federal government's

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October 6, 1981
Re: Hearings on End Stage Renal Disease Program by Senate Finance
Sub-committee on Health. Hearings began on Monday, Sept. 28.

paying large sums of money to non-resident or minimally qualified physicians while down-grading the quality of medical care for this group of patients.

From the list of subject headings on which the sub-committee expects to hear testimony, I have excerpted the following which I believe should be included in the responsibilities of the networks:

1. The identification of and prevention of abuses.
2. The availability and need for clinical and program data.
3. The implementation and results of mandated studies and experiments.
4. The effects of past and present program reorganizations.
5. The impact of staffing levels and training on cost and quality of care.
6. The capabilities of intermediaries and carriers to control cost.

I strongly urge the preservation of a meaningful regulatory system through the End Stage Renal Disease Network Coordinating Councils and through the Health Care Financing Administration. The cost of the networks (less than $5,000,000) compared to the cost of the overall program (by 1983 over $3,000,000,000) is feasible, and the benefits both to the patients and government are enormous.

Sincerely,

K. Trevor From Jr., M.D.

KTF/mu

198 Hickory Grove Drive
Larchmont, New York 10538
September 23, 1981

Robert E. Lighthizer, Chief Counsel
Committee on Finance
Room 2227
Derksen Senate Office Building
Washington, DC 20510

Re: ESRD Hearing - 9-28-81

Dear Mr. Lighthizer:

I am writing in support of End Stage Renal Disease Networks. I have been a social worker in a home dialysis program since 1968 and have been actively involved in the Network program as a social work representative since its' inception. It is my opinion that Networks have rendered invaluable services to patients.

Dialysis is probably a process unique in medicine, in terms of the amount of time spent at each treatment, in the lifelong nature of it and the fact that without constant treatment, these patients would die. Patients who receive their treatments in dialysis centers, are treated three times weekly, and spend 4 to 5 hours each time having their treatments.

The planning and supervisory controls that ESRD Networks provide for this very dependent and vulnerable patient population is vital. The Network charge is to "provide access to care" and to monitor the quality of care. Many of us remember the days when patients were chosen for or denied this treatment process by "Selection Committees." Few of us would like to return to that because treatment centers are so poorly planned that one area has too many centers and others have too few.

If Network funds are terminated there will be at least four areas of service that will no longer have a formal structure from which to operate:

I. Planning
One of the primary Network functions is to plan for the provision of services to ESRD patients. Network 25 (New York) delegated this responsibility to its' Executive Committee, which included in addition to volunteer physicians, nurses and social workers all experienced in ESRD care, patient representatives. This committee held open

Continued......

meetings and hearings as to the quality of care proposed facilities could provide, assessed its ability to provide service efficiently, and looked at geographic location in relation to the density of patient population and accessibility of the center to transportation.

II. Quality of Service
Medical Review Boards are charged with evaluating the quality of care that ESRD centers provide. These interdisciplinary bodies and the Medical Care Evaluations that were developed were designed to evaluate by peer review the quality of care provided.

III. Cost Containment
The cost of home dialysis is significantly less than center dialysis. For the first time in several years patients entering home dialysis programs increased. It is probably due to the response of the Networks to its charge to assess how patients are selected for the various ESRD treatment programs. A review of this decision making process brought the attention of ESRD Units to its mechanism of the provision of information in this area and thereby probably stimulated patient interest in self-care.

IV. Grievance Mechanism
Center dialysis patients are dependent on a life long time consuming treatment process in which areas of conflict can easily develop. The patient's life literally depends on sustaining a relationship with the ESRD Unit and its staff. A formal grievance mechanism is the means by which patients may address problem areas in a neutral setting, verbalize concerns and anticipate that some response will be forthcoming. It therefore formally gives the patient the "right" to seek redress and the means by which to seek it.

Although some of the areas of responsibility outlined above may be picked up by state or local agencies, there are none who have the expertise in the ESRD program which Networks have developed in their five years of existence.

I, therefore, urge the committee to continue supporting Networks in light of their valuable contributions to patient care.

Sincerely,

Phyllis Getlan, A.C.S.W.
Social Worker

TESTIMONY OF ESRD NETWORK #8
SUBMITTED TO
SENATE FINANCE SUB-COMMITTEE ON HEALTH HEARINGS
ON THE END STAGE RENAL DISEASE PROGRAM
September 28, 1981

INTRODUCTION

The Network Coordinating Council of ESRD Network #8 in Iowa and Nebraska, believes that its efforts have had highly significant positive impact on the quality of end stage renal disease care and the efficiency with which it is delivered in our area. We maintain that our experience, along with that of other Networks, supports the need for the continuation of Networks as the most cost-effective mechanism for the collection of data vital to assessing quality of care, and cost control. Further, our experience demonstrates the cost-effectiveness of our direct involvement in implementing quality assurance mechanisms; encouraging home dialysis, transplantation, and rehabilitation; monitoring utilization, triaging, and patient care planning; developing long range strategies for distribution of ESRD services and resources; promoting patient participation; and fostering professional interchange.

A conservative estimate of the cost savings resulting from our Network's activities has been computed at $1,500,000 to $2,000,000 annually. When compared to the relatively small amount required to operate the Network, it can be seen that the Network saves well over 15 to 20 times its administrative costs yearly. This is without regard to the many other direct and indirect benefits which result from Network activities for which it would be difficult to set a financial value.

Following is a summary of selected important accomplishments of Network #8 during the past year.

QUALITY OF CARE ASSURANCE

The major thrust of Network activities during the past year have been directed at assuring the quality of care provided to ESRD patients supported by the Network's patient data system. The Network's Medical Review Board completed numerous reviews of patient care. The following are highlights of these reviews.

- Screening and monitoring referrals for home dialysis and transplantation has aided in assuring that all patients are being carefully evaluated and placed in the treatment setting most suitable to their needs. In addition, by studying reasons why patients are found to be unsuitable for these treatments, the MRB (Medical Review Board) is able to concentrate efforts on these areas and work to remedy such situations and problems where possible.

- By presenting factual survival rates of renal transplantation in Network #8 to providers and patients, a better, more educated decision whether to choose this therapy for any particular patient is made. Survival rates in Network #8 have proven to be above or equal to results both nationally and internationally.

- Facts revealed by the Network data profiles (i.e., one-year mortality rates for ESRD patients, morbidity information, success/failure rates according to age, sex, diagnosis, etc.) have led to peer discussion of sensitive areas such as the appropriateness of treatment selected.

- The Network performed a study on organ recovery identifying problem areas and recommending improvements. Several of those recommendations were implemented and subsequently an increase in organ recovery in the Network resulted.

- Professionals have commented that simply knowing a special study is underway and that their care is being monitored by a knowledgeable professional group of practitioners keeps them "on their toes" and makes them more sensitive to certain issues. Improved documentation in patient records of outcomes of home dialysis and transplantation evaluations resulted from two studies.

- Concentrating efforts on increasing home dialysis and transplantation and strongly encouraging the therapies have been cornerstones of Network #8's goals. Subsequently, both home dialysis and transplantation have increased each year which has resulted in demonstrated cost savings and an enhanced quality of life for patients.

- Writing criteria and discussing variations found in medical care evaluation studies builds rapport and consensus among renal physicians.

NETWORK IMPACT ON COSTS

Another direct result of the Network's activities has been a measurable impact on the cost of treatment. The treatment of all newly diagnosed ESRD patients in the Network is reviewed by the Medical Review Board assuring that there is documented medical justification for initiating dialysis, that the frequency of treatment is the minimum required to maintain the patient and that the patient is evlauated and referred where appropriate for less costly home dialysis or transplantation therapies. If, for example, a patient may be maintained for a time on conservative treatments rather than immediate referral to dialysis, a potential savings of over $2,000 could be realized for each month dialysis can be delayed. Similarly if a patient's blood chemistries and dietary compliance are stable, it may be possible to maintain the patient on two weekly dialysis treatments rather than the usual three resulting in a savings of nearly $9,000 per patient per year.

Even more dramatic savings are possible by referral for home dialysis and transplantation where savings of up to $24,000 per patient per year are possible. Network #8 currently maintains one of the highest rates for home dialysis in the county, 26%, (nearly double the current national rate) and within the Network an average of over 20% of newly diagnosed patients are transplanted, again higher than the national average.

The extent of possible savings by the referral of patients for home dialysis and transplantation is illustrated by the following evaluation of the estimated two year treatment costs for the 277 ESRD patients diagnosed in the Network during 1979.

ESTIMATED TWO YEAR TREATMENT COSTS
FOR ESRD PATIENTS DIAGNOSED IN CALENDAR 1979
ESRD NETWORK #8

Total ESRD Patients Diagnosed during 1979		277
Status 12/31/80:		
Center Dialysis	96	
Home Dialysis	44	
Functioning Transplant	72	
Death	55	
Other (regained function/transferred)	20	
Total patients this group being treated (less deaths and other) as of 12/32/80	202	

Estimated Average Costs of Treatment

Incenter Dialysis	$28,000/year
Home Dialysis	$22,000/year
Transplantation	$28,000 1st year $4,000/year subsequently

Year One, Estimated Treatment Costs

Center Dialysis 96 patients x $28,000/patient/year	$2,689,000
Home Dialysis 44. patients x $22,000/patient/year	968,000
Transplantation 62 patients x $28,000/patient/year	1,736,000
TOTAL	$5,393,000

Year Two, Estimated Treatment Costs

Center Dialysis 96 patients x $28,000/patient/year	$2,689,000
Home Dialysis 44 patients x $22,000/patient/year	968,000
Transplantation 62 patients x $4,000/patient/2nd year cost	248,000
TOTAL	$3,905,000

Estimated Cost If All Patients Were Treated In Center
202 patients x $28,000/patient/per year $5,656,000

SUMMARY

	All Patients Treated In-center	Actual Costs	Potential Savings
Year One	$5,656,000	$5,393,000	$ 263,000
Year Two	$5,656,000	$3,905,000	$1,751,000
	Total potential savings for two years		$2,014,000

Source: ESRD Network #8 Patient Characteristics Study, February 1981
Network #8 Five Year Plan for ESRD Services, May 1981

Although this analysis is based on the simplest case and does not include all actual variables, the potential for cost savings is still significant. For each patient intiating home dialysis, the annual savings is at least $6,000. Similarly every patient who receives a transplant can potentially realize an annual savings beginning one year post transplant of $22,000 for each year the graft continues to function. Though the example probably somewhat overstates the savings, since at least a portion of these patients may have elected these treatment options anyway, even a total savings of only half this amount for approximately every 200 patients has a profound effect on the overall cost to Medicare.

Currently Networks are not directly involved with the reimbursement for services by Medicare. However, the existing Networks do have both the data and expertise to even more directly impact on costs. Comparison of the detailed Network patient data, for example, with reimbursement claims could aid to minimize abuse. Networks could also assume the responsibility for annual facility inspection now contracted to state agencies resulting in even further savings.

SUMMARY

It is apparent that Network #8, as well as other Networks, contributes far more in direct and indirect savings to Medicare than the 0.4% of the Medicare ESRD budget currently spent for their operation. Additionally, the Network contributes enormously to the quality of care and ultimate rehabilitation of the ESRD patient. While no dollar amount can be set on the value of rehabilitation of ESRD patients, further significant savings for federal disability and other support programs are likely possible.

Networks, with their local control of quality standards and utilization of medical resources, and peer effort in cost containment, are splendid examples of reduced federal intervention and regulation. The federal government, the members of the renal treatment team, the ESRD facilities, and the renal failure patients- all have a great deal to gain from a very modest investment in the continuation of ESRD Networks.

WRITTEN STATEMENT OF THE MIDWEST ORGAN BANK, INC.

WRITTEN STATEMENT

Pursuant to public hearings held before the Subcommittee on Health, of the Finance Committee, of the United States Senate, on September 28, 1981, addressing the End Stage Renal Disease program, the Midwest Organ Bank offers the following written statement to be included in the printed record of said hearing. This statement includes excerpts taken from a Position Paper drafted and previously offered by the Midwest Organ Bank to the Subcommittee on Health of the Ways and Means Committee of the United States House of Representatives in August of 1980.

Public Law 92-603. Prior to 1973, federal funding for kidney transplantation was not available. On October 30, 1972, Public Law 92-603 was signed into law to be effective July 1, 1973 . . . . Not until July, 1974, did the Social Security Administration promulgate and publish simplified reimbursement procedures.[1] These procedures outlined the development of the standard kidney acquisition charge. This charge reflected the component costs incurred from the point of donation of the kidney until its arrival at the transplant hospital.

The method of determining reimbursement at the local level was equally as simplified as the procedures outlined in the above-described Intermediary Letter. Annually, the administrators of the Midwest Organ Bank would meet with representatives of the local intermediary, The Blue Cross - Blue Shield Insurance Company, to review the proposed budget for the up-coming fiscal year. This budget included the costs of the various services to be performed by the Midwest Organ Bank in conjunction with a projected number of kidneys to be retrieved during the fiscal year by the organization. After review and upon final approval by the intermediary, the Midwest Organ Bank would operate under this budget during the year without further regulation or interference by either the intermediary or the Health Care Financing Administration. The Midwest Organ Bank would bill the requesting transplant hospital for services rendered, and would be reimbursed by that hospital based on the charges derived from the approved budget.

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[1] Department of Health, Education and Welfare; Social Security Administration, "Part A Intermediary Letter No. 74-23," July, 1974.

The overall effect of Public Law 92-603 on the Midwest Organ Bank was favorable. The method of reimbursement emphasized a budgetary process which culminated in a contractual arrangement among the Midwest Organ Bank, transplant hospitals and the local intermediary. This arrangement provided the flexibility necessary for the growth of the organization and the expansion of its services. The success of the Midwest Organ Bank is evident in the numbers of kidneys retrieved since 1973, and the corresponding success in locating suitable recipients for transplantation.

Conversely, no apparent suggestion was made to the administrators of the Midwest Organ Bank that the program was ineffective either locally or nationwide. Furthermore, prior to passage of Public Law 95-292, there was no indication that the program was fiscally abused by the various agencies and laboratories.

Public Law 95-292. On June 13, 1978, Public Law 95-292 was signed into law to become effective October 1, 1978. This legislation amended prior Public Law 92-603 . . . . Following passage of the legislation, supporting regulations regarding the new method of reimbursement for agencies and labs were not published until December 14, 1978. The final rule took effect on February 12, 1979, and published in the Code of Federal Regulations, 42 CFR Part 405 . . . .

ANALYSIS OF PUBLIC LAW 95-292

Interpretation of Legislation by Health Care Financing Administration and Intermediary. It is obvious that after passage of Public Law 95-292, that the intent of The Department of Health, Education and Welfare through the Health Care Financing Administration (HCFA) was to bring the independent agencies and labs into a direct regulatory scheme. The statement compatible with this intent may be found in the Federal Register of December 14, 1978, cited earlier.

> . . . At the present time, services furnished by such organizations (organ procurement agency and a histocompatability laboratory), if they are not part of the transplant hospital, are billed to hospitals, which pay the charges shown on the bill. The charges then become allowable costs of the hospitals. Transplant hospitals have no authority or basis for determining the reasonableness of the charges made by the organ procurement agency (OPA) or the histocompatability laboratory. Moreover, at present the charge made by the OPA or laboratory is *not reviewed by the Medicare intermediary* to determine whether it is excessive. *The potential, therefore, exists that the Medicare program is paying too much for these services* . . . .[2] (emphasis supplied)

From this statement, it appears that HCFA did not recognize or was not aware that the budgets of the independent agencies or labs were being received by the local intermediaries under Public Law 92-603, as previously pointed out at p. 1, *supra*. Furthermore, because of the "potential" of these organizations to excessively charge Medicare for their services, HCFA felt it necessary to prescribe direct regulations over these agencies and labs . . . .

HCFA has also cited in support of its regulatory scheme that portion of Senate Report No. 95-714, as follows:

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[2] Ibid., p. 58370

> Under present law, pre-transplant services furnished by organ procurement agencies and histocompatability laboratories are reimbursed as in-patient hospital services at the time of transplantation . . . . however, it has not provided the program with adequate fiscal controls . . . . The bill, therefore, provides for reimbursement of organ procurement agency and histocompatability laboratory services on a reasonable cost basis.
>
> In implementing this provision, it is expected that the Secretary will apply recognized principles of cost reimbursement, obtain periodic cost reports, and provide for an intermediary hearing for an agency or laboratory which disagrees with a cost determination . . .[3]

Taking cue from this language, HCFA obviously determined that by employing the existing provider regulatory scheme would be consistent not only with the statutory language but with whatever congressional intent may be derived from Senate Report 95-714. Private conversations held between representatives of HCFA and the Midwest Organ Bank on June 4, 1980, further indicated that the administration did not feel any other method of regulation or reimbursement would be appropriate.

The history following passage of Public Law 95-292 seems to bear out another facet of this analysis. On June 26, 1978, the Midwest Organ Bank laboratory was visited by three representatives of the Social Security Administration, said individuals apparently charged with the task of formulating proposed regulations to implement the legislation. During this visit, there was no clear indication of the type of regulations to be drafted. On September 7, 1978, representatives of the independent agencies and labs were briefed by HCFA as to those regulations. What came about from the visit and subsequent meeting was, again, a brief regulation dovetailing independent agencies and labs into a prior set of regulations without a great deal of regard whether such organizations could survive under this system. Seemingly, the lack of knowledge on the part of HCFA as to the method of operation of independent agencies and labs contributed to this course of action.

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[3] Senate Report No. 95-714, "End Stage Renal Disease Program," 95th Cong., 2nd Sess., p. 12 (1978). (See also House Report No. 95-549, "End Stage Renal Disease Program," 95th Cong., 1st Sess., p. 14 (1977).)

No evidence exists that a separate or alternative means of reimbursement or regulatory scheme was ever considered. The entire regulatory scheme implemented rests on the comments quoted from the Senate Report, supra.

Part of the regulations addressed to the independent agencies and labs requires the execution of a written agreement with the Secretary in order to be reimbursed. The regulation requires that pursuant to this agreement, the participating agency or lab must allow the Secretary to designate a national intermediary "to determine the interim reimbursement rate payable to the transplant hospitals for services provided by the OPA or laboratory and to make a determination of reasonable cost based upon the cost report filed by the OPA or laboratory . . . ." 42 CFR 405.436(c)(ii) The impact of this language is twofold.

First of all, instead of the use of local or regional intermediaries as was the case under Public Law 92-603, one designated intermediary would administer the program nationwide. The apparent reasoning is that consistent with the regulatory scheme to be implemented, there is a need for national administration of the E.S.R.D. program as it pertains to independent agencies and labs. Such administration would include the standardization of laboratory test procedures. Additionally, HCFA felt only one intermediary would be necessary considering the limited number of in-

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dependent agencies and labs.[4]

Secondly, the regulatory language cited provides authority to the intermediary to determine the costs of the agencies and labs. HCFA has deferred broad discretion to the intermediary in the decision-making process which would appear consistent with HCFA's determination that national administration of the program is necessary. However, the extent of the intermediary's authority is vague in reference to its decision-making, and will be further discussed in the next section of this paper.

Pursuant to the regulation designating a national intermediary, HCFA contracted in May, 1979, with the Aetna Life Insurance Company to perform the administrative functions. Since that designation, the position of the intermediary has been to interpret the regulations and formulate policy for reimbursement. Evidence of this position may be found in various Medicare Bulletins published since May of 1979.

Because of previously described regulations, the intermediary determined that the implementing policies and detailed methods of reimbursement should be in accordance with the Provider Reimbursement Manual, HIM-15, Part I. This determination was published in the Medicare Bulletin dated May 30, 1979. As noted in this Bulletin, limitations as to various cost and income items are covered.

Further functions to be performed by the intermediary have become more apparent during the course of its administration. First of all, the development of a cost report was delegated to the intermediary; and secondly, the audits of the agencies and labs were likewise to be performed by the intermediary. Finally, based on private discussions between representatives of the Aetna Company and the Midwest Organ Bank, the intermediary would develop standardized test procedures, and, conjunctively, standardized costs or cost formulas.

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[4] Department of Health, Education and Welfare; Social Security Administration, Part A Intermediary Letter No. 79-17, May, 1979.

Interpretation of legislation and regulatory scheme by the Midwest Organ Bank, Inc. Principly, the Midwest Organ Bank bases its analysis and interpretation of Public Law 95-292 upon the language of that portion of the legislation which states as follows:

> . . . (which amounts shall not exceed, in respect to costs in procuring organs attributable to payments made to an organ procurement agency or histocompatability laboratory, the costs incurred by that agency or laboratory) . . . . Public Law 95-292, Section 1881(b)(2)(A). (emphasis supplied)

As emphasized, the basis for determination shall be the "costs incurred" by the agency or lab. The Midwest Organ Bank interprets this language to be that the primary thrust for determining the basis for reimbursement shall be the costs which the agency or lab defines in order for that organization to do business. Conversely, the Midwest Organ Bank does not interpret this language to mean that the basis for reimbursement shall be the costs imposed by a regulatory agency.

Under the prior statute, Public Law 92-603, a budget was submitted by the Midwest Organ Bank to the intermediary, said budget based on what the organization perceived as its costs for performing the services to be rendered during the fiscal year. Through essentially the medium of bargaining, the intermediary and Midwest Organ Bank arrived at a mutually agreeable basis for costs. The new legislation does not appear to necessarily alter that approach. On the contrary, the initial and primary factor to be considered is the costs determined by the agency and lab incident to the performance of their services.

The legislative history behind Public Law 95-292 does not indicate that the transplant program was necessarily ineffective or uneconomical. The general feeling appeared to be that the program was generally successful, but tempered with concern of the rising costs and the need to eliminate disincentives.

> . . . Although this program has been successful in meeting the need of renal disease patients for medicare insurance protection, the committee has concluded that improvement can and must be made both to contain rising program costs and to enhance its effectiveness . . . .
>
> In the case of transplantation, the major disincentives are related to certain inequities in the present entitlement provisions. H.R. 8423 would help to overcome these disincentives to transplantation in four ways. First, it would extend the post-transplant period of coverage from the present 12 months to 36 months. Second, it would provide for the immediate resumption of coverage without a waiting period whenever the transplant fails. Third, it would modify present law by beginning coverage initially with the month of hospitalization if transplant surgery takes place within the following two months. And fourth, it would provide coverage for the expenses incurred by live kidney donors.
>
> . . . it has been estimated that the elimination of these disincentives could significantly increase the percentage of patients undertaking transplantation. And in view of the fact that transplantation is far less costly than lifetime dialysis, such a development would result in considerable program savings over time.[5]

There does not appear any indication that independent agencies or labs should be brought into the regulatory scheme now implemented, nor any reasons stated that one might infer such regulations are necessary. Moreover, the bulk of the legislative history seems directed toward the dialysis program and the concerns raised therein. This would be consistent with the statutory language authorizing the Secretary to " . . . prescribe in regulations any methods and procedures to (i) determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals determined to have end-stage renal disease . . . ." P.L. 95-292, § 1881(b)(2)(B). No such language exists within the statute which authorizes the Secretary to exercise the same or any regulatory function over independent agencies and labs.

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[5] Congressional Record - House of Representatives, "End Stage Renal Disease Program," p.H9257, September 12, 1977.

A question arises as to the style in which organ procurement agencies and histocompatability laboratories are incorporated into the statute. This language of incorporation is parenthetical and only modifies those amounts which are paid to transplant centers. By modification, the transplant centers are restricted in their payments to agencies and labs, those amounts which reflect the costs incurred by the agencies and labs. The Midwest Organ Bank perceives this style of drafting to indicate something less than the type or extent of regulation implemented against the independent agencies and labs.

In the previous discussion describing HCFA's interpretation of the statute, the administration apparently relies on Senate Report No. 95-714 as primary support of its regulatory authority. (See p. 4, supra.) The portions of that report quoted (as interpreted by the Secretary) purport to give the Secretary authorization to implement existing methods of reimbursement and regulations. The Midwest Organ Bank questions the origin of these statements. Because the language is identical with that of House Report No. 95-549, it appears that the Senate Committee on Finance and the House Committee on Ways and Means adopted and incorporated a policy statement conceived by HCFA and approved by the Committees. If this is the case, such policy is contra to the actual intent of Congress without an opportunity for input or defenses which could be advanced by those organizations which are consequently regulated. The policy statements are made without at least a prima facie showing of the necessity for such regulation.

It should be noted that the Congressional Record of the Senate incorporates portions of the Senate Report No. 95-714.[6] The excerpt printed into the Record does not include the above-cited section in the Senate Report discussing the utilization of existing reimbursement mechanisms. In fact, an analysis of both the House and Senate Congressional Records on P.L. 95-292 does not indicate any limitation on methods of reimbursement or the necessity of regulations such as those now implemented.

What effect will the regulatory scheme implemented under P.L. 95-292 have on the independent organ procurement agencies and histocompatability laboratories? Primarily, there are four effects which will result.

A. The regulatory scheme will either eliminate or drastically reduce certain costs necessary and incident to the improvement and efficiency of the program. Examples of these items are as follows:

1. Research and Development. The provider regulations and reimbursement policy generally eliminate research and development as reimbursable items. However, research and development are absolutely necessary to the continued scientific and community improvement in transplantation. Such research costs related to maintaining and expanding the state of the art including development of reagents used in serological typing procedures which are a necessary process of laboratories, and the continued search for a better perfusate and maintenance of preservation techniques. Additional costs are necessary to develop and expand the kidney retrieval programs by establishing new retrieval centers with new communities and hospitals. These examples are but a natural incidence to the operation of independent agencies and labs, and, therefore, should appropriately be continued by such organizations.

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[6] Congressional Record - Senate, "End Stage Renal Disease Program," p. S5224, April 10, 1978.

2. Public and Professional Education. The statute authorizes the Secretary to "...conduct a comprehensive study of methods for increasing public participation in kidney donation and other organ donation programs." P.L. 95-292, §1881(f)(4). The Midwest Organ Bank has concentrated on an effective public education program since the inception of the organization. The costs of this program are necessary to increase an awareness on the part of the public for the need for organ donations. Through its cooperation with the local Kidney Foundation affiliate, the Midwest Organ Bank can certainly substantiate the positive effect of this program by review of the increase in retrieved kidneys since 1973. In spite of this successful public education program, the intermediary has, both privately and publicly, expressed its reservations regarding such programs. The potential limiting of funds for such purposes was expressed in the Medicare Bulletin, dated June 19, 1980.

Equal attention must be given to the professional education programs undertaken. The costs of these programs are necessary to physicians, intensive care personnel, emergency room personnel, operating room personnel, clergy and other medical personnel who may come into contact with the donor or donor's family.

3. Capital Expenditures. Such costs relate to new equipment, replacement; and updating of equipment to stay abreast of the advancing state of the art. Under the current regulatory scheme, the provisions for such accounts would be eliminated. Although HCFA and its intermediary have indicated that the independent agencies and labs would be reimbursed for interest on loans and depreciation on equipment, this method of reimbursement will not work because independent agencies and labs do not generally have the financial resources to use as collateral in securing loans from financial

institutions. Whereas these independent organizations rely primarily on the E.S.R.D. programs for their business, strict cost reimbursement for depreciation and interest is inadequate without some additional rate of return to adjust to technological changes. In this respect, the independent agency or lab differs from the normal provider (hospital, skilled nursing facility or home health agency) in the sense that a provider generally has a large private or non-governmental business segment from which to draw funding for such expenditures. As previously stressed, regulating independent organ procurement agencies and histocompatability labs as providers is inequitable.

4. Rate of Return. The statute provides that in the case of proprietary providers and renal dialysis facilities, provisions may be allowed for a reasonable rate of return on equity capital (emphasis supplied) P.L. 95-292, §1881(b)(2)(C). HCFA and its intermediary have allowed for a rate of return on equity capital for independent proprietary labs. A question arises whether an allowance for such labs is consistent with the statutory language. However, if independent labs are allowed a rate of return, an equity basis for return would generally be insufficient for purposes of capital expenditures as described above, and insufficient for purposes of incentives. Since most such agencies and labs have no substantial equity or can foresee a growth in equity under the reimbursement mechanism previously described, little can be gained from a restricted return on investment.

B. The regulatory scheme will impede the development of growth and expansion of independent organ retrieval agencies into areas not presently serviced by such organizations. The intent of the statute is to increase transplantation in order to decrease the number of patients on lifetime dialysis. Many areas of the country are denied access to retrieval centers which now exist. The Midwest Organ Bank has demonstrated the effectiveness of establishing out-lying retrieval centers im community hospitals. Without an incentive or a seed-money concept, many under-developed areas will remain neglected. The regulations or implememting policies do not recognize the need to invest in such programs.

C. The regulatory scheme, as interpreted by the intermediary, will adversly affect the non-renal portion of the business of the independent lab. Because of the nature of the work performed within the histocompatability lab, other services are available outside the area of renal testing. Pursuant to the proposed cost report to be used, the intermediary has advised all independent labs that certain tests performed for renal-related patients which may also be performed for non-renal-related patients must have the same charge. Medicare Bulletin dated March 28, 1980. Referring to the "non-billable" situation as described on pages 1 and 2, supra, the effect of this regulation is obvious. If pre-transplant tests performed for patients in dialysis units are charged off to patients in transplant centers, the costs of the tests paid for are inflated. If the same test is performed for a non-renal patient, under the current policy formulated by the intermediary, the same inflated cost must be charged that patient. Such an inequity will price the organization out of any non-renal-related business which it might be able to perform. According to the intermediary, based on private discusssions, this problem is only unique to the Midwest Organ Bank. However, the real issue is the propriety of the federal government exercising control over the business of the independent lab which may be unrelated to the E.S.R.D. program.

D. As indicated on pp. 8 and 9, supra, the present legislation speaks more to dialysis than to transplantation. Historically, dialysis has been the dominant means of survival for patients with chronic renal failure. An increase in renal treatment costs is more obvious in the area of dialysis than transplantation. Congress intended through P.L. 95-292 to create incentives for patients to utilize home dialysis which would reduce the per-patient cost of dialysis treatment by nearly one-half. However, the emphasis on incentives for dialysis may have a negative impact on transplantation. There is an apparent stagnation in the number of recipient candidates presently on dialysis, even though many more dialysis patients are suitable for transplantation. A decline in the recipient pool will adversely affect the usage of kidneys available for transplant, especially if the number of donors continues to rise. Again, such an effect of the legislation and supporting regulations is contra to the long-range goal of cost-containment. A one-time cost for a successful transplant is certainly more economical than a life-time dialysis cost.

E. It has been an apparent attitude on the part of HCFA and its intermediary that the rising costs of transplantation are associated exclusively with the independent agencies and labs. A large portion of the kidney acquisition charge billed to the transplant hospital includes costs associated with the donor hospital and the services rendered by it in the removal of the kidneys. The Midwest Organ Bank contends that it is these costs which are increasing faster than the costs directly attributable to the independent agency and lab. Yet, the agency or lab has no means of controlling or regulating the indirect costs even though these costs are computed into the organ procurement agency's kidney acquisition charge. By virtue of the regulations, the independent agency is cast into the position of paying increasing costs while having its own charges regulated. Certainly, Congress did not intend to regulate only the organ procurement agency without regulating the other participating institutions in the kidney retrieval effort.

F. Under the current regulatory scheme, the employment of a single intermediary raises additional concerns. There appears to be some movement to standardize procedures in lab testing and to further standardize the costs from lab to lab. The Midwest Organ Bank deems such an effort to be virtually impossible considering the evolving methodology within the histocompatability area. New tests and new procedures for existing tests are constantly being developed, and therefore standardization would likewise undergo constant change. Furthermore, the potential dictation of procedures by the intermediary constitute infringement into the medical decision-making, absolutely contra to congressional intent. As noted in the Congressional Record.

> The last thing we want is to give further Federal entities - be they network organizations or HEW - further arbitrary control over the practice of medicine. We have had enough experience with the health planning guidelines in recent months to make it clear that we do not want arbitrary, bureaucratically established "standards" imposed on local treatment decisions...[7]

In order that the intermediary attempt to standardize various areas of the program, there would be required various studies to determine procedures and the associated costs. Such studies would undoubtedly cost the federal government an undetermined amount of funding. The actual savings to the government in cost-containment of independent agencies and labs would appear to be extensively reduced by the on-going reimbursement control proposed.

These examples of the effects from the regulatory scheme which has been implemented indicate the long-range hardships that will certainly hinder not only the future of the kidney transplantation but also the future of the independent agency or lab as a business enterprise. As is the case of most providers, there is generally enough non-Medicare business to support those areas which are restricted or denied under the provider regulations. On the other hand, in the case of independent agencies and labs, there is relatively little non-renal income to support the costs necessary to the total operation of the agency or lab. Because the focus of the independent organ procurement agency and histocompatability lab has traditionally been in the renal disease area, and furthermore, because if the disparity between providers and independent agencies and labs in terms of sources of income, other alternatives must be addressed in order that the E.S.R.D. program survive.

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[7] Congressional Record - Senate, "End Stage Renal Disease Program," p. S8194, May 24, 1978.

Some of these concerns have been addressed to HCFA but with a negative response.

POSITION OF THE MIDWEST ORGAN BANK, INC.

The position of the Midwest Organ Bank is primarily based upon the relationship between the federal government and the independent agencies and labs. As previously discussed, the relationship between Medicare and the independent organizations, under P.L. 92-603, was based upon a bargaining agreement. During the period of that statutory existence, a dramatic increase in the number of kidneys retrieved by independent organ procurement agencies occurred. During the same period of time, the independent histocompatability labs developed new techniques for more successful matching between donors and recipients. Under the regulatory scheme now instituted by HCFA, both the independent agency and independent lab would be strangled in their present course of business.

What the Midwest Organ Bank proposes to seek on behalf of all independent agencies and labs is an emphasis on the "independent status" of such organizations. That is, one viable alternative to the present interpretation of the statute is a relationship based on more of a contractual arrangement among the independent agencies and labs, the transplant centers and the intermediary, coupled with removal of those agencies and labs from the provider regulations. This relationship would be based on more of prospective bargaining within a budgetary process similar to the method employed under P.L. 92-603. As noted in the analysis of that prior legislation, supra, there was little evidence that the method used was ineffective or necessarily wasteful, and, furthermore, Congress concluded that the E.S.R.D. program was generally successful during its formative years.

Congress did concede that the cost of the program was dramatically on the rise. The congressional position was one of cost-containment through the emphasis of incentives for home dialysis and the elimination of disincentives for transplantation. Whether this position authorizes the use of regulations is the primary issue to be addressed. It is the contention of the Midwest Organ Bank that the dramatic increase of regulation to counter the dramatic increase in costs belies the intent of Congress and the ultimate goal of the E.S.R.D. program. The Midwest Organ Bank further contends that determining and establishing reasonable costs on an annual contractual basis would serve the need for cost-containment, at the same time, maintaining the independent status of the agencies and labs. In support of its contentions and position, the Midwest Organ Bank offers the following:

A. A contractual arrangement can be as cost-effective as that envisioned under the regulatory scheme implemented. On an annual basis, each independent agency and lab would offer a proposed budget to be reviewed by the intermediary, HCFA, and possibly the regional transplant centers. The approach to this procedure would be based on a "bare-bones" budget including some reasonable rate of return. A rate of return is necessary to provide agencies the incentive for increased retrieval activity. Under the present system, where revenue must equal expenses, there is absolutely no incentive for increased organ retrieval.

Following submission of a proposed bare-bones budget, it would be reviewed by all sides to determine the reasonableness of the costs of the services to be rendered. Such a review would resemble a prospective informal audit of the renal costs and the cost structure involved in the renal-related services to be rendered by the agencies and labs. Such a procedure would eliminate the need for subsequent formal audits and cost reports. Following negotiation of an approved budget, a contract or memorandum of agreement would be executed based on that budget for the fiscal year.

The Midwest Organ Bank believes that this arms-length relationship with the federal government would not only be at least as cost effective as a relationship built on regulations, but would further provide the necessary incentives for increased transplantation. One additional comment merits serious consideration. If Congress desires to reduce the long-term costs of the program, the reduction in the number of dialyzed patients is critical. The obvious means is through transplantation. In order to increase transplantation, some degree of fiscal latitude must be allowed the independent agency and lab to promote not only the increase in donor population, but also to improve the technology incident to successful matching between donor and recipient.

B. The Midwest Organ Bank seriously questions the employment of a single intermediary to administer a national program. This seems to deviate from the normal Medicare practice of utilizing local intermediaries. If the position described above was assumed, it would appear logical to allow the regional Medicare intermediaries and the regional HCFA offices to review budgets and execute annual contracts with the independent agencies and labs.

Utilizing local intermediaries has two primary advantages. First of all, the local intermediary is generally familiar with the medical customs and practices within its region. In drafting and submitting annual budgets, the Midwest Organ Bank is confident that its local intermediary would base its review of these budgets on a rational analysis of the reasonable costs incident to the Midwest Organ Bank's operation. Secondly, in the event budget projections were inaccurate, the local intermediary could more easily and quickly react to make budgetary adjustments necessary to maintain fiscal integrity.

To reiterate, the use of an additional intermediary to handle the determination of costs nationwide seems inefficient and uneconomical from an administrative standpoint. Under P.L. 92-603, no evidence has surfaced that utilizing local or regional intermediaries was ineffective. Therefore, the Midwest Organ Bank adopts as part of its position, the need to review the utilization of a national intermediary, both in reference to cost and effectiveness.

C. Upon approval of an annual budget and execution of a contract, the costs of services agreed to would actually reflect the customary charges of the independent agency or lab for the ensuing year. These charges would be recognized not only by the regional transplant hospitals, but by any transplant hospital or dialysis unit which may utilize that particular organization's services. Moreover, any dialysis unit not located within a transplant hospital, and which requires transplant tests for recipient candidates should be allowed to pay for these tests. This feature would alleviate the non-billable problem previously described, and would accurately reflect all costs reimbursed on a per-patient basis.

D. The independent relationship would allow the agencies and labs to conduct business unrelated to the renal program without government interference. As discussed on pages 13 and 14 supra, the proposed policy of the intermediary would force the agencies and labs to charge equally for both Medicare and private patients. Presumably, this policy is derived from the provider regulations. By removing the independent agencies and labs from these regulations, further influence in the non-renal areas would be eliminated.

The position outlined above reflects a somewhat drastic, though feasible, change in the present reimbursement mechanism. The Midwest Organ Bank recognizes that Congress might anticipate some regulation involved in reimbursement of federal money. Therefore, as an alternative position, the Midwest Organ Bank suggests a replacement of the present regulatory scheme with one tailored to the needs of the independent agencies and labs, yet, consistent with cost-containment. Such a new regulatory scheme should reflect a reimbursement of costs for certain items not included in the provider regulations. Additionally, and equally important, an incentive program must be included to encourage procurement agencies in the development of increased retrieval. Examples of those types of areas necessary to the E.S.R.D. program are as follows:

A. Research and Development. A reasonable amount of costs attributable to research and development consistent with a clinical laboratory operation is necessary to improve the methodology of histocompatability testing.

B. Capital Expenditures. A reimbursement mechanism to provide funding for capital purchases is necessary where the purchase of such items is consistent with the maintenance and growth of each independent agency or lab.

C. Public and Professional Education. Continued reimbursement of both public and professional education is necessary to increase not only public awareness of the program, but to encourage participation, particularly in the donor population.

D. Rate of Return. A mechanism for allowing a rate of return is vital in order to create incentives for increased kidney retrieval and also to allow for the maintenance and growth of the individual agencies and labs.

E. Seed Money. Funding should be allowed for agencies and labs to expand into geographical areas that are presently under-serviced by the program. This concept, where appropriate, would cultivate areas in which little or no transplantation is occurring.

This list is by no means inclusive, and only demonstrates functional and necessary areas which would become neglected under the current regulations. In order to establish a different type of regulatory scheme, input from the independent agencies and labs is crucial. If this position were accepted, it would probably be necessary for representatives of the government and representatives of the agencies and labs to convene in order to mutually establish the criteria inherent in the regulatory process.

SUMMARY

This discussion has attempted to review the history of the E.S.R.D. program from 1974 to the present. Additionally, the discussion has outlined the effects of the regulations implemented under P.L. 95-292. The Midwest Organ Bank, Inc., is quite concerned about the increasingly larger role the federal government plays in medical care. The regulation of this particular program is tantamount to an intrusion into a relatively new and evolving practice of medicine with little regard by the regulators for the ends to be served by the program. It is apparent that the administrators of the End-Stage Renal Disease program and the intermediary to which policymaking has been subrogated are destined to slash costs with little concern for the organization attempting to deliver the services, and the ultimate beneficiary of the program - the patient.

The Health Care Financing Administration has taken the attitude that regulation will somehow reduce costs. The Midwest Organ Bank contends that this argument can be dismissed summarily unless it is proven that a program regulated by the federal bureaucracy is more economical than if that activity were operated exclusively by private enterprise. What is to be gained by this type of federal regulation if the cost of the administration of the program exceeds the costs contained by implementation of the regulations? What is to be gained if the administrators of the End-Stage Renal Disease program and its intermediary continue down a course toward infringement within medical decision-making? The practice of medicine should be left to the medical practitioner, and not to the regulators.

The Midwest Organ Bank concedes that costs have risen since this program began. However, it should be noted that many efforts in kidney retrieval and transplantation are voluntary efforts, and are not reflected in the actual costs of the program. Many volunteers including physicians, clergymen and nursing personnel have contributed freely not only in community retrieval programs, but also in the counseling of the families of potential donors, and in the counseling of potential recipients who are about to undergo a major transplant operation. Stagnation of the transplant program under the present regulatory scheme would simply obliterate these efforts and destroy the goodwill generated over the years among community hospitals, transplant centers, organ procurement agencies and other individuals closely associated with either these institutions or the patients. Possibly the real issue is whether the legislative emphasis is on cost-containment or the delivery of services to the patient. The Midwest Organ Bank believes that both goals can be achieved as long as the independent organ procurement agencies and histocompatability laboratories are allowed to function as private institutions and not as governmental subsidiaries.

The trend toward establishing one governmental policy after another to regulate improvement within a particular program must receive the same concern as the rising cost of the program itself. If Congress passes legislation in order to improve a medical program, it seems only accurate that the supporting regulations be sensitive to the needs of that particular program, if, indeed, regulations are necessary. The Midwest Organ Bank and the supporting independent agencies and labs request the opportunity to register their input, and further request a review of the statutory and regulatory language interpreted by the Social Security Administration and the Health Care Financing Administration.

Respectfully submitted,

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STATEMENT FOR WRITTEN RECORD
END STAGE RENAL DISEASE PROGRAM OVERSIGHT HEARING
SUBCOMMITTEE ON HEALTH
OF THE
SENATE COMMITTEE ON FINANCE
SEPTEMBER, 28, 1981

Edmonts Linamegi, Chairperson, Consumer Committee, Michigan End Stage Renal Disease Network

Renal Networks afford a mechanism by which providers in the private sector and the federal government cooperate to provide quality care at reasonable cost to end stage renal disease patients.

The Michigan Renal Network has developed since October, 1977, into a forum in which renal providers and patients from university programs, private and community-based hospitals, proprietary clinics, multi-service kidney centers, and single renal service programs have grappled with their divergent views and philosophies to begin to establish norms. Although there had been a long history in Michigan of renal physicians coming together to participate in renal advisory and scientific boards, the federally assigned responsibility of local long range planning and quality assurance within a multidisciplinary/consumer environment required the evolution of new relationships.

As the Network concept developed in Michigan, recognition that renal patients/consumers have a legitimate place in the shaping of federal and local health care policy emerged. Renal patients have developed a means to articulate their position and philosophy of renal care. Renal patients serve on policy and decision-making committees with providers to develop and implement the goals and objectives of the national ESRD Program.

The return on federal investment into Network funding is substantial since federal monies are expended almost exclusively for administrative support. The physicians, administrators, nurses, social workers, dietitians, technicians, and renal patients are usually not paid for their professional time. Over the past year in Michigan alone there were approximately 2520 man hours "donated" during participation in 4 Coordinating Council meetings, 5 Executive Committee meetings, 10 Medical Review Board meetings, 10 Planning Committee meetings, 6 Consumer Committee meetings, 4 Membership Committee meetings, 2 By-Law Committee meetings, 3 Finance Committee meetings, and 4 sub-committee meetings. At a $20 per hour composite rate, $50,400 of professional time was provided gratis.

The Michigan Renal Network has set and applied criteria and standards to address the following elements of patient treatment:

- annual patient informed consent for dialysis
- psycho-social evaluation of patient and family
- patient understanding of dietary instruction
- patient understanding of vascular access care
- documentation of treatment plan when safe blood chemistry parameters are exceeded
- interdisciplinary team approach to renal care
- patient and family member input into long term care plan
- patient right to change modality of treatment without prejudice to current treatment or access to facility
- patient understanding of rights and responsibilities
- documented preoperative workup prior to renal transplantation surgery
- pre-transplant surgery documentation of red blood cell compatibility and negative crossmatch information
- post-transplant discharge criteria
- acceptable length of stay for renal transplant hospitalization

Medical Review Board monitoring of patient long term care planning in Michigan provides an effective means of documenting that treatment options are offered to all patients and may, therefore, be responsible for the altered utilization of self-care modalities. The gradual increase in the home dialysis population may well be an example of the Michigan Network carrying out the intent of Public Law 95-292.

The Michigan Network has participated in a medical decision-making study with the University of Toronto to analyze attitudinal factors influencing treatment modality selection. Network committees have developed standardized reporting forms in concert with the national Medical Information System and the local Michigan Kidney Registry. With the implementation of the new reporting system, morbidity data will now be available by treatment modality. Network committees are already analyzing mortality data, patient origin and destination reports, and renal disease incidence and prevalence reports, to identify trends, deviations, potential problems and suggest changes in practice, when appropriate.

The strength of the Network concept has been its de-centralized, local control of ESRD policy to address federal program objectives. The funding and operation of ESRD Networks are integral parts of cost-effective and coordinated administration of the ESRD entitlement program and represent an alternative to centralized governance and regulated norms.

This Congress has the choice of supporting the ongoing data collection and quality assurance efforts of Networks, or authorizing far greater sums to duplicate this effort on a federal scale. Funding of Network administration can be accomplished at a rate of only sixty cents ($.60) per patient treatment.

I urge you to support the continuation of Renal Networks.

Renal Physicians Association of New Jersey

The Renal Physicians Association of New Jersey, having had a long and deeply involved history of participation in ESRD care, both at the state and federal levels, herein submit this testimony as representative of the renal physicians' views engaged in the care of ESRD patients in New Jersey.

This statement will follow the outline developed in the Senate Finance Committee's release and questions contained therein.

UTILIZATION AND ACCESS

1. **Do the existing minimum utilization rates reflect current accepted medical practice? Are they being applied in a reasonable manner? Are they needed to control the cost of the program and/or the quality of care?**

The existing minimum utilization rates are not reflective of current medical practice. In fact, HCFA has withheld application of the minimum utilization rates for over two years now, with no demonstrable adverse effect on the program. Such rates have no effect on either quality or cost controls.

It is recommended that minimum utilization rates as currently applied be abandoned.

2. **Does the certificate of need requirement effectively control the cost of the program and/or the quality of care? Is the requirement necessary? If the requirement is eliminated, what would be the effect on the cost of the program, quality of care, and patient access to facilities and physicians?**

Although there are conflicting data on the cost-effectiveness of CON requirements, a totally open, unplanned renal program would be counterproductive. There is a necessity for a basic minimum number of stations, treatments, and concentration of skilled staff to effect a quality program. If the ESRD program, inclusive of both dialysis and transplantation were totally unregulated, there would be an enormous proliferation of costly, small programs. It will drive the cost of the service up, and diminish the quality of care. CON is a necessary requirement for the ESRD Program.

Negative Impact on Home Dialysis;

Further, with an unregulated proliferation of dialysis units, there would be a substantial reduction in home dialysis, probably reaching a near zero mark. In order for facilities to maintain even the minimum number of treatments in a widespread in-center dialysis proliferation, less patients would be available for home care. The impact on home dialysis programs with an opeh, unregulated, unplanned ESRD service would be enormously detrimental. The history of this program bears this out, when prior to Medicare funding the majority of patients were treated at home. Now, only 14% are treated at home. Further, it should be stated that nowhere has there been ever demonstrated loss of access to dialysis by patients in need because of CON.

Consequently, CON, despite drawbacks, should remain intact for ESRD planning in order to maintain quality and cost-effective in-center and home care.

It is recommended that a restriction of additional dialysis units be imposed, or expansion of existing units only be permitted through CON until an improved performance in home dialysis patient population is effected. CON could be used in a practical manner to improve home dialysis rates. In those areas where existing facilities continue to have very low home dialysis rates, new facilities should be added which can demonstrate the ability to effect the accomplishment of successful home dialysis.

3. What barriers restrict patient access to facilities and physicans of their choice? What barriers restrict access to home dialysis and to transplantation? Should these barriers be eliminated? And if so, how?

4. Should patients be free to choose a physician independently of their choice of treatment setting? Should the program be modified to foster open market competition among providers of treatment?

To our knowledge, there are no barriers restricting patient access to facilities. A patient may not always have his physician of choice, but such is not unique to the renal program. Facilities and health care institutions are designed by their governing boards to develop the highest levels of quality care and cost-effectiveness. The pattern of staffing and the quality of care derived from that staffing is the responsibility of the governing body, not the federal government.

The Medicare statutes (42 USC/395) state that no federal officer or employee shall exercise any supervision or control over the practice of medicine "or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services, or to exercise any supervision or control over the administration or operation of any such institution, agency, or person."

It should be pointed out to the Committee that an enormous body of case law now exists upholding the rights and the responsibility of the governing boards of health care institutions to select and staff their programs in the manner most efficient for their needs. The right of governing boards to enter into exclusive contracts have been repeatedly upheld by courts.

Numerous cases, including dialysis, and others involving various other specialized areas of medicine have similarly involved and upheld closed staffing. See, Adler v. Montefiore Hospital Association, 453 Pa. 60, 221 A.2d 634 (1974) (cardiac catheterization); Bank v. Palo Alto-Stanford Hospital Center, 234 Cal. App. 2d 377, 44 Cal. Rptr. 572 (1965) (radiology department); Letsch v. Northern San Diego County Hospital District, 246 Cal. App. 2d 673, 55 Cal. Rptr. 118 (1967) (radiology department); Centeno v. Roseville Community Hospital, 167 Cal. Rptr. 183 (Cal. App. 1979) (radiology department); Powsner v. St. Joseph Hospital, No. 5279 (Cir. Ct. Washtenaw Cty., Mich., 1977) (cardiac catheterization and ECG interpretation); Dattilo v. Tucson General Hospital, 23 Ariz. App. 392, 533 P.2d 700 (1975) (nuclear medicine). Lewin v. St. Joseph Hospital of Orange, 82 Cal. App. 3d 368, 146 Cal. (hemodialysis).

Thus, while some may speculate that sound patient care requires open staffing, the great weight of judicial authority buttressed by expert testimony has held to the contrary.

In an internal study done by HCFA, (To Secretary, January 21, 1980), the agency cautioned against getting involved in the staffing question. The Memo stated first that:

> "Thus far, we have not been able to obtain data to indicate that an "open staff" requirement would further any of these purposes, (i.e., cost-effectiveness, quality of patient care, health and safety, continuity of patient care, encouraging home dialysis)."

The Memo went on to point out that federal intervention into staffing policies puts the government in the role of:

> "...assuming the responsibility for the quality of care provided to patient by that staff."

Most importantly, HCFA pointed out that there are good reasons for letting each facility make their decisions regarding staff privileges.

> "We do believe we are not in a position to substitute our judgement for that of a facility's governing body."

Such a conclusion is in keeping with a recent legal decision (Virginia v. Palisades General Hospital, 80, N.J.), wherein the court stated:

> "Neither reason nor authority persuades that a hospital is foreclosed from utilizing an exclusive group contract as a device to maximize the quality of a hospital-based service."

In certain instances, it is possible that a totally open staffing requirement could deny patients access to care because of an inability to take any more physicians on, leaving the patients, with only their physician of choice to choose from, potentially without care.

Open market competition among providers of care will not effect the cost of this program. History has shown that this type of economic thinking does not work in medical care. What will occur with a totally free, open competition market is a dimunition in quality with no change in cost.

Barriers to Home Dialysis and Transplantation

The principal barrier to home dialysis has been, and will continue to be, lack of sufficient economic incentives. Some of this has been rectified under PL-95-292, but not sufficiently. The barrier to home dialysis will only be removed when there is an economic advantage for providing this service, far greater than has been the current situation of economic disadvantage to both the provider and the patient. However, in another area, for which immediate relief is available, HCFA has been at fault because of their obstinancy in permitting physicians receiving reimbursement under the Standard Method not to receive reimbursement for the home patients under the Alternate Reimbursement Method. The Bureau of Program Policy of HCFA has a deaf ear on this issue. There is no sound reason for denying physicians reimbursement under the ARM for their home patients. As a result, those physicians on the Initial (Standard) method of reimbursement have absolutely no incentive to send patients into home care.

In another area, there has not been a refinement of the regulations to encourage CAPD. HCFA has not properly dealt with the CAPD issue, and as a consequence, this type of home care has not grown. Again, the deficiency lies with the Bureau of Program Policy in addressing this issue.

A major barrier to transplantation is physician concern over the outcome. Improvements in graft and patient survival will result in better physician acceptance. However, more research funding is needed in the areas of transplant immunology, and a national effort for organ procurement is required.

PROGRAM MANAGEMENT

1. What effect have prior reorganizations had on the management of the program? Will the current reorganization adversely affect the program? Should there be a focal point for the program?

This is an area of surely needed congressional action. Unquestionably there should be a focal point for this program. There had been created a Special Programs Branch in HCFA, with an ESRD program staff. The current HCFA administrator, on the advice of the Bureau of Program Policy, is breaking this branch up.

The ineffectiveness of the Office of ESRD was not with its staff, but with its line of authority. They were continually thwarted by the Bureau of Program Policy in their attempts to get problems resolved. This program is extremely complex and has elements of reimbursement, operations, regulations, that are mind-boggling. It is absolutely essential that the program have a well-educated and seasoned staff. However, there is a constant turnover of staff through transfers and reorganizations. By the time one group develops a level of expertise, there is a reorganization.

The New Jersey Renal Physicians Association strongly recommends a separate and distinct branch within HCFA for ESRD program policy and management. To this end, even if congressional legislative action is necessary, a separate ESRD branch should be established.

2. How well have the intermediaries and carriers performed under the ESRD program? Who is responsible for assessing their performance under the program and by what mechanisms? How can the effectiveness and efficiency of intermediary and carrier ESRD operations be improved? Should their ESRD operations be consolidated?

There has been wide divergence of opinions regarding intermediaries and carriers. Some have been very poor, and some very good. Many, however, do not maintain an up-to-date knowledge of ESRD regulations and reimbursement matters.

The New Jersey Renal Physicians Association recommends consolidating some intermediaries and carriers by regions, but allowing providers to choose which carrier they want for reimbursement payments. This would produce competitiveness and efficiency among carriers, something needed more than among providers.

3. How is program integrity assured? What are the results of recent studies by the Bureau of Quality Control? What has been done to identify program fraud and abuse? What are the most serious issues related to program integrity, and fraud and abuse?

The Bureau of Quality Control has conducted some studies recently, one of which was in New Jersey, and its methodology was unscientific, biased, and of such poor quality, that its results were useless. Quality measurements are difficult to ascertain with a good data base; with a poor data base, it cannot even be considered. HCFA needs to improve its data collection system, permitting the collection of usable data statistics by facilities for various simple quality parameters, such as mortality, hospitalizations, repetitive access surgical procedures; with the ability to then monitor individual programs, whose patterns of care do not conform to the norms of care.

There have been statements unofficially made in the press about potential fraud and abuse in the ESRD program. Any persons, facilities, or groups engaged in fraudulent activity should be prosecuted to the fullest extend by law. However, the entire ESRD program, its providers of services and facilities should not be cast in a discriminatory light by innuendo because of unfounded suspicions. Essentially, those guilty should be exposed and dealt with, and the honest providers, which encompasses the vast majority, should not be cast into the same lot.

The most serious issue related to program integrity is the matter of agency responsiveness to the needs of the patients and the providers. HCFA has all the statutory authority it needs to audit facilities, to gather true cost data, and to prosecute true offenders. If it does not exercise its authority in these matters, then there is no one to blame but the agency. However, it must accomplish this with equity and integrity.

4. What have the networks accomplished? How effectively have they addressed quality of care, treatment setting, and treatment modality issues?

Networks have not accomplished what they had been mandated to do. The problem lies with insufficient staff and funding to accomplish the enormous goals laid before them. They have not dealt effectively with quality care, treatment settings, and modality of care issues. The networks' main strength has been in data collection.

5. Are networks needed to collect data, ensure quality care, or participate in facility planning? Are there alternative methods to carry out these functions? Should network operations be consolidated or eliminated?

Networks per se are not needed to ensure quality, or participate in facility planning. Those states with effective departments within the state health departments can accomplish these tasks. An alternative is for the federal government to provide block grants to the state health departments for the purpose of establishing ESRD programs with sufficient staff to conduct these data, planning, and quality care functions in a joint effort. Network operations could be concentrated on data collection and quality care assurance if block grants are not practical.

QUALITY OF CARE

1. Are facility certifications and on-site annual surveys necessary to assure quality care? Are there less costly alternatives to the facility survey and certification process?

At the present time, facility certifications and on-site annual surveys are the only functions available to independently assess quality of care. Unless an alternate system is developed, facility certifications and surveys should remain in place because without these, in some instances, there would be nothing.
Any system of surveys less costly to the federal government would either have to be taken over by the States, or voluntarily at the local level. Neither appears to be practical at the present time.

2. What deficiences have been identified through the survey/certification process? How many facilities were not certified or were decertified? For what reasons?

The answer to these questions are unknown or perhaps known only the HCFA.

3. How should quality of care be monitored? What data is needed to assess quality?

The most effective monitoring of quality care is through on-site review by independent peer groups. However, this is extremely difficult because of the manpower needs and potential enormous cost. Nevertheless, if data acquisition were adequate and included such parameters as (a) mortality rates; (b) hospitalization rates; (c) recurrent need for access surgery, (d) rehabilitation rates; and (e) self-care or home dialysis rates, then reference points would be established against which patient goals, such as those currently being developed at the network level could be matched. Medical review staff personnel could then be used to review individual programs whose data analysis do not conform with either the norms or the goals. Such an approach would assure some degree of quality care, with monitoring performed at the local level. However, very specific and very technical patient care evaluation would be virtually impossible to monitor and to evaluate on any large scale basis.

4. What staff qualifications and/or training are needed to ensure quality care? What levels of staffing are necessary to provide adequate care?

Properly trained and highly qualified professional staff remain the single most important element for a quality care program. Physicians should have a minimum of two years of training in an approved nephrology program offering ample experience in acute and chronic hemodialysis, home dialysis, CAPD, IPD, and transplantation before becoming eligible to assume the care of ESRD patients. Staffing patterns in a hemodialysis unit is difficult to standardize, but, in general, the following staffing patterns for direct (non-supervisory) patient care would be reasonable: (Staff:patient)

In-Center Dialysis
Assisted Care: 1:3.5
Self-Care: 1:6
Self-Care Dialysis Training: 1:1.5
Acute Intercurrent Illness
(i.e. In-patient Care): 1:1.5

PROGRAM DATA AND RESEARCH

1. Does the medical information system provide useful, accurate, and complete data to program managers? Is reliable and complete reimbursement, cost, treatment modality, and patient characteristics data available in usable form?

The answer to these questions is in essence no. Although some data is beginning to become available, its reliability is still very questionable, particularly in regards to cost. Simple patient characteristics such as age, sex, and race, are probably reasonably accurate.

2. How can the data for effective program management be collected? What sanctions are available to assure complete, reliable data are provided?

The most effective way to collect data, and assure facility compliance is to require data submission as a prerequisite to reimbursement. However, carriers will need additional staff support to monitor this aspect and to collect and tabulate the data and efforts should be expanded in that direction.

3. How should clinical research data needs be satisfied?

Research needs should be ascertained through the usual channels of communication with the scientific community.

4. What is the status of the studies and experiments mandated by P.L. 95-292? How many agencies are involved in these studies and experiments? How are their efforts coordinated?

5. What studies and/or experiments are the most promising with respect to reducing program costs and/or improving quality of care? Have they been given priority?

These questions can only properly be answered by HCFA. However, any studies undertaken by HCFA should be carefully planned, scientifically sound, and applied equally. Further, their conclusions should be derived from statistically significant results, not merely personal feelings or prejudices.

STATEMENT OF DANIEL J. JONES, MEMBER, PATIENT ADVISORY COMMITTEE, END STAGE RENAL DISEASE NETWORK 23

Honorable Members of the Subcommittee on Health,
Senate Committee on Finanace
United States Senate

October 16, 1981

Dear Sirs;

I would like to thank you and your staff, for the opportunity to appear before your Subcommittee at hearings held on the End-stage renal disease program, on September 28, 1981. Your concern for this program and willingness to elicit the opinions of patients in developing legislation, is indicative of your awareness of the contribution that patients can make in this most important area.

I particularly appreciate this awareness since it is my belief that the success of any treatment program for victims of end stage renal disease is dependent upon patients access to information, and right to choose the kind of treatment that is appropriate to their own needs. For this reason I believe that patients must be able to play a role in policing as well as policy-making for renal disease treatment programs. Through ESRD Networks, Patient Advisory committees can, and have, had influence in providing options that offer patients the oportunity to make the appropriate choices for their own treatment. I suggest that whatever decisions you make about this program take into consideration the important role of these committees in improving the availability of choices to patients.

Such choices include out-patient or self-dialyis at home or in a center, as well as transplantation. I cannot stress enough the importance of the contribution that patients can make in this regard. To accomplish what we have all set out to do - that is, provide renal patients with high quality, cost-effective care - it is essential to determine, examine and eradicate barriers to patient choice. For example, while home, or self-dialysis is appropriate for some patients, it is not feasible for others.

Reasons for this include physical, emotional and intellectual limitations, as well as lack of financial resources necessary to adapt one's home to the structural alterations required to accomodate a hemodialysis machine. The latter (structural impediments to home-dialysis) may be overcome by perfecting alternative types of dialysis (such as CAPD) which require little structural accomodation, or by allowing some reimbursement for structural renovations necessary to accomodate home hemodialysis. However, the physical, emotional or intellectual limitations of individual patients are barriers that are less amenable to such simple solutions. These are endemic problems that are associated with renal illness, and/or an individual patient's abilities. Attached is an excellent article on the subject of the fears of dialysis patient's, which may help to explain some of these problems and the physical and emotional stress that is a part of every dialysis patient's life. I hope that you will consider including this as part of your hearing record.

Another choice that patients should have the opportunity to make, is that of transplantation. While this alternative is appealing to many patients, it may not be available to them for a variety of reasons. Some patients simply do not have the option of transplanation because their physical condition will not allow it, or because of difficulties with tissue matching and the unavailability of donor organs. Others fear the consequences of immunosuppresive drugs and the potentially life-threatening illnesses associated with the weakening of the body's immunity system.

Still, others hesitate because they fear the evenutal loss of medicare insurance in the face of on-going medical costs associated with transplant care and medication. This concern may be addressed by extending the period of Medicare insurance coverage for the life of the kidney, as was recommended by the Patient Advisory Committee of Network 23, at your hearing. However, the other barriers to transplantation are much more difficult to overcome although we all remain hopeful that the miracles of medicine will find a way.

In summary, I would again like to thank you for the opportunity to appear before your subcommittee. I appreciate your interest in the views of those of us who are the recipients of the benefits you have made available through the Medicare, End-stage renal disease program. I support the maintenance of networks, with patient advisory committees playing an integral role. I hope that as you make the many legislative decisions facing you, you will continue to call upon the expertise and experience of those who are being treated - the patients. I, and my fellow advisory committee members, will be glad to render any further assistance that you might need in this regard.

Sincerely,

Daniel J Jones.

Daniel J. Jones, Member
Patient Advisory Committee
End Stage Renal Disease Network 23.

Unexpressed Fears of Dialysis Patients

By Mark Reinsberg

Hemodialysis, from a patient's point of view, is far preferable to death, but it is rarely a happy, uneventful routine at the best of out-patient centers. For this gift of life, a set of disagreeable circumstances must somehow be normalized, and a number of fearful, painful things have to be submerged in the subconscious. So it is the essence of good nephrology nursing to understand those anxieties which lie so close to the surface of relationships in a dialysis center.

In discussing the unexpressed fears of chronic kidney patients, I do not presume to speak for all users of every form of dialysis at all stages of treatment. And I must emphasize that the following is not a description of what can go wrong at artificial kidney centers, but of what patients continue to fear when everything seems to be going *right*.

Cleansing of blood, as everyone professionally connected with hemodialysis well knows, is always a volatile situation. For that reason, I will begin by turning the question slightly around: What are the things dialysis patients pray do not happen? My list is limited to matters which good nursing can affect in one way or another. Ignored are important worries in other spheres such as finances, cosmetics, transportation or the hazards of daily life. The bundle of anxieties could be enlarged or reduced, but I have arbitrarily settled on these nine items, several of them very closely related.

1. The clumsy "stick"
2. Access failure
3. Blood loss
4. Mechanical failure
5. Cramps and crashes
6. Denial of credibility
7. Bad sterile technique
8. Hepatitis
9. Staff problems

• Clumsy venipuncture is the gateway to every patient's private hell. The insertion of a 16-gauge butterfly needle into a mature access may be entirely painless or it may be a torment, depending on the nurse's skill and sensitivity. Worse than causing pain, a clumsy stick may perforate the vessel, cause infiltration, and necessitate another cannulation. And another. And another. It is not uncommon for a patient to be stuck four or five times before an adequate flow of blood is obtained.

True, the problem is often in the state of the patient's blood vessels. But the skill to connect plastic tubing with human arm does vary among nurses and does not seem to have much to do with competence in other facets of nursing. Poor stickers are generally unaware they're poor because few patients will bluntly say so. But there is usually a consensus on who is good, bad or indifferent at sticking. An anonymous patient survey might yield results startling to the staff.

I believe a nurse can improve venipuncture skills by cultivating an interest in the body signals of patients during the procedure. *Asking* the patient is also an honorable approach. A veteran patient, having been stuck so many times during years on the machine, has some hard-won opinions as to what points of attack will work best . . . for him, at least. (The use of xylocaine is not at issue here. But if a patient who usually does without the pain-killer suddenly requests it, it may be because he has doubts about the capacities of the person putting him on.)

• Failure of a major access is another persistent worry of the dialysis patient. Fistula, graft or shunt, the access is the navel of his existence. A threat to its reliability is a threat to his life. Although surgeons may visualize a dozen alternative sites and strategems should one access fail, the patient foresees all too clearly the trauma he will be repeating. He would like to feel that his nurse has a

Mark Reinsberg vacationing in Stuart, Florida.

conservationist attitude toward his accesses.

This goes beyond care and patience in venipuncture. It extends to tourniquet technique, to avoidance of accidental severeal of arterial and venous lines, to monitoring of venous pressure, to care in returning blood at the end of the run. There should be discussion of rotation of sites for rest and healing where possible, and of course proper bandaging.

Obviously, an access can fail through no fault of nursing. Many fail over the course of time through simple wear and tear. But some accesses that appear marginal will hold up if patiently nursed along, and here is where some extra care and solicitude are worth a great deal.

- Blood loss is unavoidable in dialysis. This is ironic because kidney patients have lost some of their ability to replenish red cells. While it is impossible to return all blood after treatment, and patients realize this, unnecessary losses are deeply resented.

Some cells are destroyed in the artificial kidney, some remain in the flushed tubing, there is some clotting, there is some leakage from the wounds. Blood must be drawn periodically to obtain chemistries. Depending on the policy of the unit, some blood may be sacrificed in the arterial stub. It's a few cc's here, a few cc's there, but for patients with hematocrits in the low 20s, these are significant losses.

Patients worry about this attrition, and would like to see it minimized. Their heaviest fear is for massive blood losses such as those which can occur when the trap clots, when a needle falls out unnoticed, a line connection parts, or a coil ruptures.

A defective coil is the manufacturer's fault, of course, not the nurse's, and if she has fully tested the coil before using it she has done her duty. But often a center experiences a high percentage of coil failures in a particular shipment and is tempted for economy's sake to use up the entire lot. Some responsible person has to set tolerance limits and adamantly refuse the remaining coils.

Patients suspect that clotted lines may sometimes be the result of miscalculation in heparin dosage. There are patients who dread falling asleep while being dialyzed for fear that no one will notice that a needle has fallen out, quietly creating a pool of blood underneath their recliner. I have personally seen a coil explode, literally, spraying a fountain of blood to the acoustical ceiling tiles.

Beyond saline I.V. to replace volume, the only immediate remedy for massive blood loss is transfusion. Here again, the question is *how* immediate.

One of the tests of a dialysis center is the willingness of its staff to stretch to obtain blood on an emergency basis. At one center a patient was sent home one evening after *three* successive coil failures, without transfusion. (Coincidentally, he died that night of "some heart problem.") And yet I have seen nurses or nephrologists personally pick up and deliver blood on late winter nights in order to protect their patients.

- A certain number of machines are always malfunctioning whether in the pumps or the circuitry, halting treatment. At most units the nurses are able to deal with superficial mechanical hitches, but there are usually only one or two people with the technical know-how to make on-the-spot repairs. When those people are off duty the only recourse is to use another machine, if one is available, or to put in an emergency call to the technician or to the manufacturer's representative. Increasingly, good nursing at dialysis centers includes mechanical skill and the power of improvisation.

Patients fear failure of electrical power where there is no back-up system, and failure of central dialysate batching systems. They would like to know what the center plans to do in case of fire or a bomb threat. (I've experienced two of the latter at a unit in Fairfax, Va.) Nonambulatory patients wonder what will happen to them if fire breaks out in a high-rise elevator building. Of course, the prior question is whether dialysis should be permitted below or above groundlevel, or in units that have no back-up power system.

- Patients dread the onset of cramps in their legs or abdomen. Even if quickly remedied by saline or hypotonic, they may be acutely painful. They are hard to anticipate and can come upon the patient suddenly, agonizingly. Legs turn into pretzels of muscular spasm. Or vomiting occurs.

The reaction time of nurses in these situations is all-important. It is sometimes enough to place the patient's feet on the floor, to turn down the pump speed or to massage the leg muscles. As to vomiting, I am always surprised that some nurses would rather rush a basin and clean-up towels to the patient who always gets nauseated in the middle of his run rather than devise a strategy to head off this reaction.

Some patients fear they will "crash," lose consciousness, as blood pressure drops. A patient can tilt himself back in his recliner at the onset of dizziness, but rarely is he able to administer saline to himself while blacking out. Again, the nurses reaction time is a measure of performance. But the approach appreciated more by a patient is monitoring of BP with knowledge of his propensities, and heading off the danger with infusion of saline.

- Denial of credibility means simply that a nurse does not entirely believe, or attach much weight to, the complaint of a patient. Indeed, some patients are always complaining about trivial or imaginary things . . . some of the time. Credibility is at stake when a patient claims he's getting sick during his run or is beginning to feel cramps, yet his BP is unchanged from previous readings. Or it may be that the patient, claiming chest pains or exhaustion, asks to have his dialysis cut short.

The nurse's dilemma is that early termination may leave the patient with inadequate chemical clearances, or that a saline bolus may add to a patient's fluid overload. She wonders just how severe the problem really is, and whether or not to withhold these measures for a time. From a patient's point of view this is doubly distressing: he's not only convinced there will be more acute suffering in the next minute but he is dehumanized in that he is not believed.

It takes months, sometimes, for a patient to build up his credibility – usually involving dramatic evidence along the way. This is one reason why changes in staff or a move to a different center arouses anxiety in a patient: it takes so long to "educate" the new people. Credibility is one of the comforts of being a long-term patient at a center; the label of complainer is something to be dreaded.

- Patients are afraid of careless sterile techniques. They have little else to do during their five hours of treatment three times a week but watch what is being done by the staff. They become acute nurse-watchers. They observe instances of sloppy asepsis: the use of contaminated items, failure to wash up or put on a new set of gloves, casualness in cannulation, and so forth.

Patients understand that many things have to be done in haste at a dialysis center, where multiple crises may stretch staff resources to the limit. But they have been taught to fear infection. They see sloppy sterile technique during routine periods with unforgiving eyes, even when they lack the presumption to protest.

- Curiously, patients fear hepatitis for some of the least important reasons. They vaguely realize that it may be a medical disaster for them. But uppermost in their minds are the social problems hepatitis will create. To become HAA Positive means that it will be almost impossible to travel because so few centers accept transient patients who are Positive. Hepatitis has the effect of imprisonment, along with other ramifications for family life.

Furthermore, it means quarantine measures at the center and loss of flexibility in scheduling. Because of the mystery of the infection process, patients are afraid to be seated anywhere near a Positive patient or even a machine that is reserved for Positives. They fear contact with members of the staff assigned to treat the quarantined patients. They wish for the virtually impossible: to be in a hundred percent Negative unit.

- Patients are made very nervous by staff turnover. It creates uncertainty about the quality of their treatment. They are sensitive to staff problems, and worry about resignations, replacements, temporary substitutes, and friction among personnel. Patients realize that nurses can also get sick, can have their own problems, but they don't want them brought to the center. For example, they feel put upon when a nurse brings a young child to run around the center during her shift for lack of other arrangements.

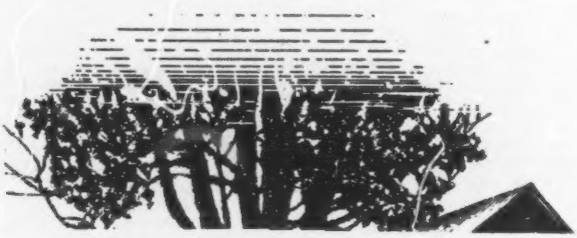
Patients are also aware of the disparity of earnings between nursing staff and doctors. It disturbs them, not only because of the inequity but because it, too, poses a threat to their well-being. When a good nurse (and it is always a good nurse) leaves to accept a better offer elsewhere it means encountering a new nurse and the re-arousal of all the unexpressed anxieties.

As I suggested at the beginning, it is not enough to identify the things dialysis patients worry about in their treatment. Nurses and therapists under their direction should understand the degree to which the anxieties may be lessened or compounded by staff attitudes or actions. Over the years I have been dialyzed in ten out-patient centers in five states. In most of these units I have experienced high levels of skill and dedication. The best units were those displaying the greatest understanding not only of the patients' obvious needs but of their hidden fears. ■

NAPHT News

May 1981

Dedicated To Kidney Patients
And Their Second Chance At Life



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NEPHROLOGY AND INTERNAL MEDICINE

November 4, 1981

Stephan E. Lawton
c/o Pierson, Ball and Dowd
1000 Ring Building
1200 18th Street, N.W.
Washington, D.C. 20036

Dear Mr. Lawton:

This is a follow-up to our phone conversation earlier this week. In my opinion, the issue of stabilization of sick uremics should not be a factor in determining reimbursement rates for outpatient dialysis units, since this stabilization is almost always done on inpatients. In other words, any patient sick enough to be considered unstable is not released to outpatient treatment until he is stable.

In the early days of the ESRD program, the new reimbursement mechanisms forced many hospitals to give up their dialysis units and encouraged the formation of new independent units. Nephrologists who had to make the transition from one practice environment to the other (and I include myself in this group) were concerned that patients would be unsafe. We quickly learned that this was not so, however. All those patients who were formerly treated in hospital-based units quite readily made the transition to independent units without any difficulty. I believe it is only the rare patient whose condition is just unstable enough to require proximity to hospital facilities without actually requiring hospitalization.

Once again, I would challenge those representing the hospital side of this argument to present some data to indicate that their patients are in some way sicker than those seen in free-standing units.

On a related subject, I am enclosing some information which came across my desk today. As you know, in many areas and particularly here in Southern California, the labor situation is such that we are required to use registry personnel for a significant portion of our nursing staff. These registries have been formed to take advantage of the area-wide labor shortage, both for general hospital work and for dialysis services in particular. The registries

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charge very high fees for providing somewhat less than satisfactory service, for all of the reasons which usually apply to transient personnel. I am enclosing data from two different registries, and as you can see, the rates for nurses range from $30 to $40 per hour for many of the categories of service. This is very relevant to the establishment of the actual dollar figures by HCFA. Their audit data from last year are already outdated, and any correction factors that might be obtained from the Bureau of Labor Statistics are also likely to grossly underestimate the impact of these high labor costs on dialysis unit financing.

I would think that it would be of great importance to show these documents to the members of the Senate Finance Committee staff who are presently attempting to set a level for reimbursement.

Once again, don't hesitate to call back for clarification on any of these issues.

Sincerely,

Martin G. Rosenblatt, M.D.

MGR:jm
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EXPERIENCE OF COMMUNITY PSYCHIATRIC CENTERS IN REDUCING HEALTH CARE COSTS UNDER THE RENAL DIALYSIS PROGRAM

On November 1, 1980, Community Psychiatric Centers, Inc., an independent provider of renal dialysis services, entered into a contract with the Hamot Medical Center, Erie, Pennsylvania whereby CPC would assume the responsibility for outpatient renal dialysis services in the hospital. The following chart represents the situation at the Hamot Medical Center before and after CPC's involvement:

	BEFORE CONTRACT WITH CPC	AFTER CONTRACT
Number of Patients	66	40*/
Per Treatment Charge	$205	$150**/
Nursing Staff	30	15
Staffing Ratio	Approximately 1.5 patients per nursing staff member	2.5 - 3 patients per nursing staff member
Number of Hours Spent for Treatment	6 - 7 hours	4.5 hours
Costs Per Treatment of Supplies	Approximately $50	$ 37

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*/ After execution of the contract a group of physicians in the community opened their own clinic and some patients were transferred to that clinic.

**/ Community Psychiatric Centers is paid $120 per treatment by the hospital. The hospital is charging the Medicare Program approximately $150 for each treatment. We understand that the additional $30 will reflect rent and utilities which are paid for by the hospital.

The dramatic and immediate change in the per treatment charge to the Medicare program was accomplished by two means:

(1) A substantial reduction in the nursing staff.

(2) The purchase of supplies through a negotiated contract by [redacted] parent company.

With respect to nursing costs, the hospital had operated two eight-hour nursing shifts back-to-back, with a considerable overlap between the two. This was reduced to one ten-hour shift. The nurses now only work four days per week instead of five, which they indicate they prefer. Thus, the number of hours per day for which nurses must be paid has been reduced from 16 hours to 10 hours with no reduction in the quality of patient care. The reduction in hours per treatment has been accomplished through the purchase of new equipment which substantially reduces sterilization time, and through training staff in procedures to allow the patient to get on and off renal dialysis machines more quickly. There was previously no incentive for the hospital to improve its staffing ratios since it had been reimbursed for the costs of all staff assigned to the unit, through the exceptions process.

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